AN OBSERVATIONAL STUDY TO DETERMINE THE UTILITY OF ULTRASOUND IN PREDICTION OF ENDOTRACHEAL TUBE SIZE IN PAEDIATRIC POPULATION

This dissertation is in partial fulfilment of the requirement for the M.D. Anaesthesiology (Branch X) Degree examination of The Tamil Nadu Dr. M.G.R. Medical University, Chennai, to be conducted in

April 2016

CERTIFICATE

This is to certify that this dissertation titled " An observational study to determine the utility of ultrasound in prediction of endotracheal tube in paediatric population" is a bonafide work of the candidate Dr. REENA A PAL, post graduate student in Department of Anaesthesiology, Christian Medical College, Vellore, done under my guidance and supervision, in partial fulfilment of regulations of The Tamil Nadu Dr. M.G.R. Medical University for the award of M.D. Anaesthesiology degree during the academic period from June 2013 to April 2016.

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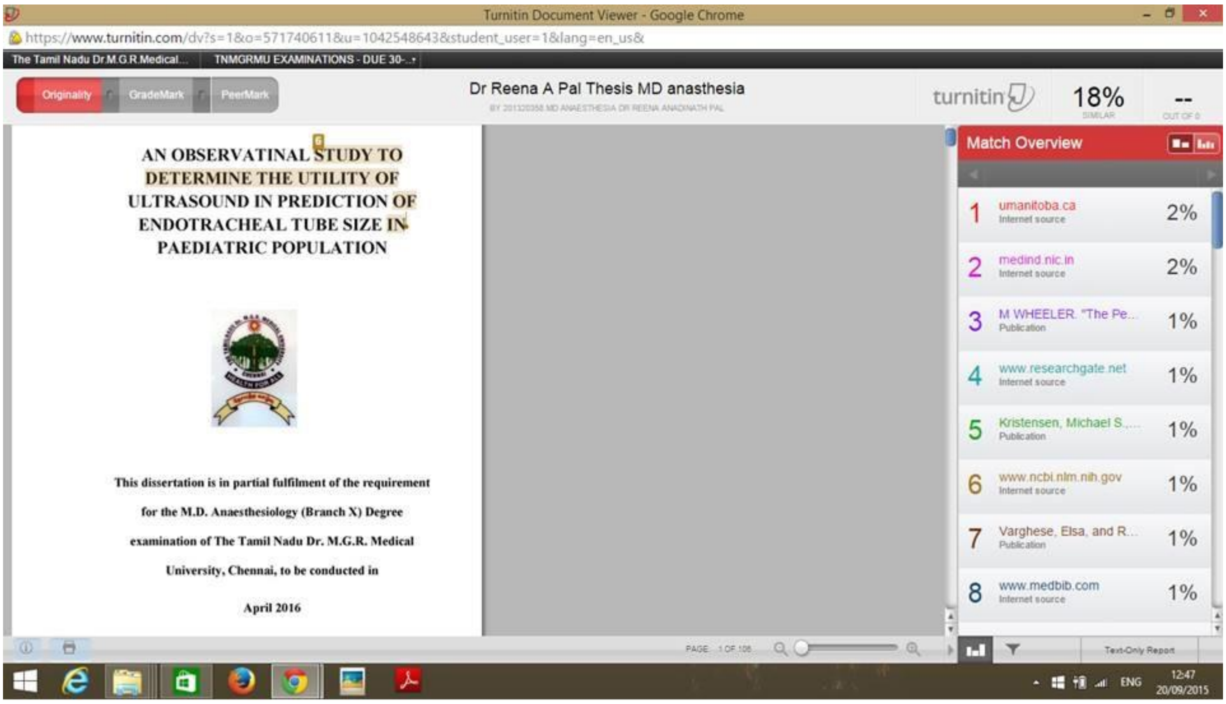
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July 24, 2014

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Sub: **Fluid Research grant project:**
Utility of ultrasonography to measure subglottic diameter for selection of uncuffed endotracheal tube in paediatric population.
Dr. Reena Pal, Dr. Ekta Rai, Dr. Anity Singh, Anaesthesia, CMC, Vellore.

Ref: IRB Min No: 8846 [OBSERVE] dated 07.04.2014

Dear Dr. Reena Pal,

The Institutional Review Board (Blue, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Utility of ultrasonography to measure subglottic diameter for selection of uncuffed endotracheal tube in paediatric population." on April 7th 2014.

The Committees reviewed the following documents:

1. IRB Application format
2. Curriculum Vitae' of Drs. Reena Pal, Ekta Rai, Anity Singh.
3. Data Form
4. Informed Consent form (English, Tamil, Hindi & Bengali)
5. Consent form (English, Tamil, Hindi & Bengali)
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Yours sincerely,

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I humbly submit this work to GOD ALMIGHTY who has given me the grace to pass through all the difficulties and without Him nothing would have been possible.

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CONTENTS

ABBREVIATIONS

ASA- American Society of Anaesthesiologists

CETT- Cuffed endotracheal tube

CT – computed tomography

CVCI - cannot ventilate cannot intubate

ETT – Endotracheal tube

ICU –intensive care unit

MRI – magnetic resonance imaging

OSAUS- Objective Structured Assessment of Ultrasound Skills

SD- standard deviation

TS – Transverse section

UETTs- Uncuffed endotracheal tube

USG- Ultrasound / ultrasonography

INTRODUCTION

One of the biggest achievements of the medical sciences is safe anaesthesia especially for children. Management of airway takes priority over the any other intraoperative intervention during anaesthesia as providing oxygen is the most important component.

Children are not the small size adults and have the distinct physiology of their own, distinct from adult which makes the paediatric anaesthesia diverse from adult anaesthesia [1]. Paediatric larynx is funnel shaped which is markedly different from cylindrical adult airway[2]. Functional residual capacity of children's airway is smaller than adults which makes them more prone for hypoxemia[2]. It is known to have proportionately higher complications if inappropriate endotracheal tube (ETT) is used in paediatric airways[3].

Age based formulas have been traditionally used for the calculation of correct size of diameter and length of ETT but it is not useful in many circumstances. Contrasting evidences have reported for and against their use in children thereby emphasising the need for better method for calculation of size of ETT[4-9]. Replacing the ETT not only causes the airway complications in children but also pose a financial burden.

It is not uncommon to find an endobronchial intubation after fixing the ETT at lip according the formula available in literature.

Imaging of airway using ultrasound theoretically could provide more accurate prediction of endotracheal tube size[10].

In the recent past, many studies have been carried out to assess the difficult airway using ultrasound[11]. Ultrasound is slowly gaining importance as screening tool for airway assessment. It is used for multiple purposes like confirmation of endotracheal tube placement and to detect oesophageal intubation, prediction of difficult laryngoscopy in obese, percutaneous tracheostomy, emergency cricothyrotomy[11]. The ultrasound method has also been verified in children[10,12-15]. Shibasaki et al assessed rate of agreement between USG and correct size ETT in 1month to 6 years old children[12]. Similar agreement was reported by Gupta et al for optimal and ultrasound guided ETT in children aged 3 to 18 years[16].

With easy availability of simplified portable devices for USG, non-invasiveness and rapid assessment can help in children where airway problems exist. This is useful especially in developing countries where uncuffed tubes are used instead of expensive micro-cuffed tubes.

This study was planned to find utility of ultrasound to predict ETT size in paediatric population, compare age based formula with ultrasound method. In this study, children under 6 years receiving general anaesthesia through ET tube were recruited after informed consent. The study group was intubated with the ET tube using age based Cole's formula and leak was estimated at 10-20 cm water. In the same patient the subglottic diameter using ultrasound was calculated before intubation. The correct size of the tube used for the patient was compared with both methods to decide which method provides the most accurate tube size required for the patient.

Similarly age based formulas for predicting tube length are mentioned in the literature. In our study for the same patient ET tube length derived from age based formula was compared to actual length of tube at angle of mouth when black line of ET tube is at vocal cords.

OBJECTIVES

- To assess the utility of ultrasonography for selection of uncuffed endotracheal tube in paediatric population
- To compare ultrasound guided method to age based formula for calculation of endotracheal tube in paediatric population
- To compare length of endotracheal tube by age based formula vs. direct visualization of black line at vocal cords and estimation of endotracheal tube length at lips.

REVIEW OF LITERATURE

PAEDIATRIC AIRWAY

Paediatric patients include preterm baby, neonate (less than 30 days of age), infants (1-12 months of age), children (1 – 12 years of age) who are not merely adults[17].

Maintenance of patent paediatric airway is single most important aspect for safe administration of anaesthesia in children. Failure to maintain a patent airway may eventually result in hypoxemia, bradycardia and even cardiac arrest causing death[3]. The most common perioperative critical incidents in paediatric anaesthesia are airway related[18]. They usually occur during induction or emergence and are more common in neonates and infants than in older children. Proper knowledge of anatomy and physiology of upper airway of paediatric patients and how it changes with anaesthesia and understanding the principles behind the management of upper airway is essential for safe conduct of paediatric anaesthesia[3].

Paediatric airway differs from adult airway in terms of shape, size, position, epithelium and supporting structures. Neonates are obligate breathers till 5 months of age[19]. It reaches adult proportion at eight years of age.

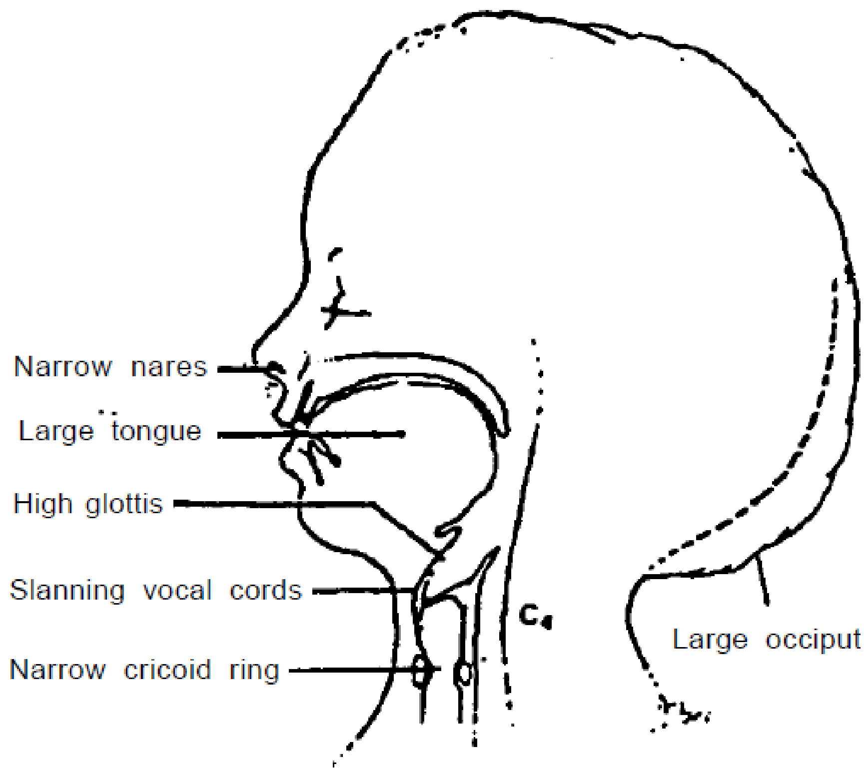

Figure 1 – Paediatric airway anatomy

The upper airway extends from the external nares and the lips to the junction of larynx and the trachea.It includes the nasal and oral cavities, the nasopharynx, oropharynx, hypopharynx or laryngopharynx and the larynx. The nasopharynx is situated directly behind nasal cavity and extends from nasal choanae to the level of soft palate. Oropharynx lies directly posterior to oral cavity and extends from soft palate superiorly to tip of epiglottis inferiorly. The hypopharynx extends from tip of epiglottis to inferior edge of cricoid cartilage[2].

Neonates and infants have proportionately large head and small neck with poor muscle control. Occiput in children is large so putting pillow under occiput to obtain sniffing position for laryngoscopy may flex head on neck making it difficult to obtain straight line of vision between eye and larynx.it is preferable to put a pad under neck and shoulder with ring under occiput to stabilize the head and help for optimum head position for laryngoscopy[19].

Infants have narrow nares. This leads to increased resistance to airflow when they are further narrowed by oedema secretions and bleeding. Infants are obligate nasal breathers in first five months of life. The angle of jaw is more obtuse in infants. Infants have non ossified palate[19].

TONGUE –Infant's tongue is relatively larger in proportion to remaining oral cavity. Hence it easily obstructs airway as tongue loses its tone after anaesthesia is given. It is difficult to manipulate tongue with laryngoscopy blade because of its large size[2].

POSITION OF LARYNX -The infant's larynx is at level of C3 - C4 which is more cephalad than adult larynx which is at C4 C5. Preterm baby larynx is at middle of third cervical vertebra[2].

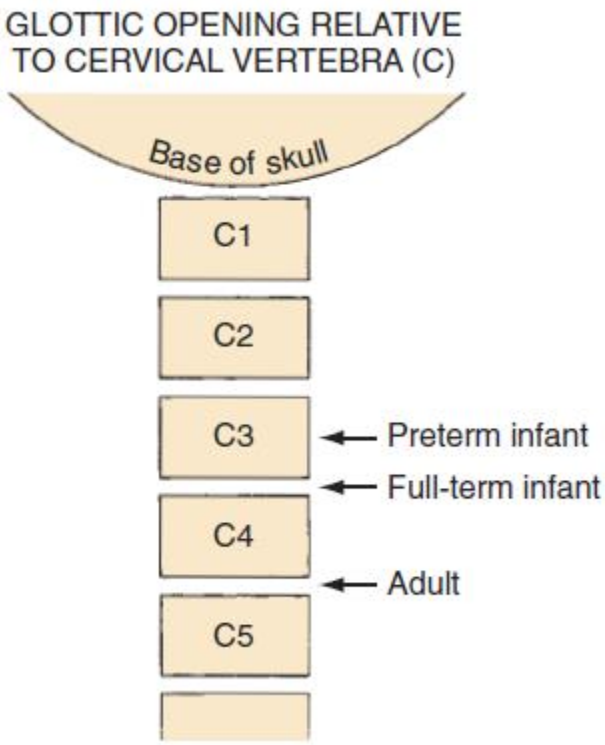

Figure 2- Schematic diagram to show the location of larynx in relation to Cervical vertebrae[2].

Magnetic resonance imaging (MRI) and computed tomography (CT) to localize airway structures confirmed that the larynx is higher (more cephalad) in children than in adults and noted that the hyoid bone is at the C2-3 level in children from neonate to 2 years of age[2].

EPIGLOTTIS

As paediatric larynx is more cephalad, distance between tongue hyoid bone and epiglottis is proportionately less than in adults making tongue to obstruct the paediatric airway[20]. Cephalad position of larynx produces acute angulation between plane of the tongue and plane of glottis opening making visualization of laryngeal structure more difficult hence difficult laryngoscopy. Hence straight blade (Miller blade) is used in infants as it lifts the tongue from field during laryngoscopy[20].

Adult epiglottis is flat, broad and axis parallel to that of trachea. Compared to adult's infant epiglottis is floppy, narrower, omega shaped, cephalad, larger and angled away from axis of trachea. Hence it is more difficult to lift infant epiglottis during laryngoscopy[21].

VOCAL FOLDS

Infant vocal cords have caudal attachment anteriorly than posteriorly compared to adults where axis of vocal cords is perpendicular to trachea. This alters the angle with which endotracheal tube enters laryngeal inlet leading to difficulty in intubation[2].

SUGGLOTTIS

Rima glottis is the narrowest portion in adults whereas in children the cricoid is considered as narrowest portion. Some recent studies state that narrowest portion in children is immediate subvocal cord level[22]. In laryngotracheal tree, cricoid cartilage is the only complete ring of cartilage, hence non expandable[2]. A tight fitting endotracheal tube may compress the trachea at this level and cause oedema; this reduces the lumen diameter of upper airway and increase the airway resistance during extubation called post extubation croup[2]. In the subglottic region the same degree of oedema is more compromising in infants compared to adults. For example, the diameter of infant cricoid is 4mm and that of adults is 8mm. E.g. if 1mm oedema forms circumferentially, the airway diameter is as a whole reduced by 2mm. This reduces the cross sectional area in infants by 75% and in adults by 44%[2]. Thus in infants the proportional increase in airway resistance is much greater than in adults. Thus it is better to leave a mild leak around the endotracheal tube than to have a tight fitting endotracheal tube. The tight fitting tube may cause mucosal oedema and increased airway resistance after extubation. Cricoid ulceration may lead to subsequent subglottic stenosis. Up to the first two years of life there is rapid growth of subglottic area after which the growth of subglottis becomes linear and at the age of 10 to 12 years the cricoid and thyroid cartilage reaches adult proportion. Thus the infant airway is funnel shaped with a narrow cricoid cartilage and a larger thyroid cartilage whereas the adult airway is cylindrical in shape[23]. It becomes cylindrical as child matures into adult [23]. Trauma causing oedema of even 1 mm in infants causes significant narrowing of the airway. On lateral wall of trachea mucosal injury and local ischaemia is caused by pressure of 25 mmHg[24].

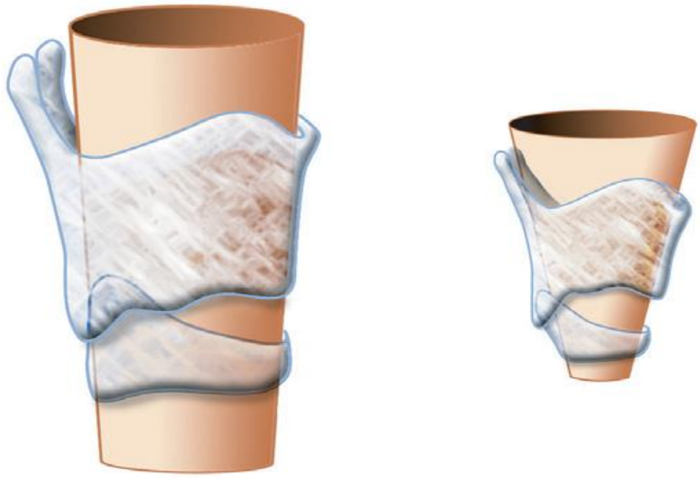

Figure 3. Shows adult cylindrical larynx and paediatric funnel shaped larynx

LARYNX

Larynx is formed by hyoid bone, and cartilages namely cricoid, thyroid paired arytenoid, corniculate and cuneiform[2]. The cartilages are suspended by ligaments from base of the skull. The cricoid cartilage articulates posteriorly with inferior cornua of thyroid cartilage. On the posterosuperior aspect of cricoid cartilage rests the paired triangular arytenoid cartilage. The arytenoid cartilage is protected by thyroid cartilage. The cartilaginous glottis accounts for 60-75% of vocal fold in children less than 2 years of age[2]. The configuration of tissue folds alters the intrinsic laryngeal muscles position and configuration influencing laryngeal function during respiration, reflex laryngospasm, during swallowing and during phonation.

The laryngeal folds consist of paired aryepiglottic fold which extends from posterior surface of epiglottis to superior part of arytenoid[2]. The cuneiform and corniculate cartilages lie within this fold. The false vocal cords (vestibular folds) extend from posterior surface of thyroid cartilage to superior surface of arytenoid[2]. True vocal cords extend from posterior surface of thyroid plate to anterior process of arytenoid. The interarytenoid fold bridges the arytenoid cartilages. The thyrohyoid fold extends from hyoid bone to thyroid cartilage.

The mucosa of larynx and trachea consists of squamous, stratified and pseudostratified ciliated columnar epithelium and it is highly vascular[2]. The seromucous glands in mucosa and submucosa lubricate the laryngeal folds. The submucosa consists of loose fibrous tissue and hence in most of the areas the mucosa is loosely adhered to underlying structures. In epiglottis and vocal cords the submucosa is scant so mucosa is tightly adhered here. Hence inflammation above vocal cords is limited to supraglottis due to firm adherence of mucosa to vocal cords. The inflammation in subglottic area is limited to subglottis and does not spread beyond vocal cords[2].

In addition infants have high diaphragm, horizontal ribs which are pliable, decreased number of alveoli . The elastic tissue in the lung is poorly developed and the lung compliance is less. The time for filling the alveoli and respiratory gas exchange is very short and adequate alveolar ventilation is maintained by high respiratory rate. The work of breathing is increased due to increase in resistance and decrease in compliance. There is increase in total oxygen consumption[2].

Infants have small functional residual capacity and are prone to perioperative hypoxemia. They have immature respiratory control and irregular breathing. Anaesthesia decreases functional residual capacity and makes them more prone to hypoxia. They are prone to upper airway obstruction early airway closure and atelectasis. They have high affinity to oxygen. Oxygen consumption is three times that of adult that is 6-7ml/kg/minute[2].

ENDOTRACHEAL INTUBATION

Endotracheal intubation is simple, rapid non-surgical technique that achieves the goal of airway management in maintaining airway patency, protecting lung from aspiration, permitting leak free ventilation during mechanical ventilation and remains gold standard procedure for airway management[3]. There are several alternatives to endotracheal intubation to manage airway like laryngeal mask airway, combitube and surgical alternatives like cricothyrotomy and tracheostomy[3]. Intubation refers to the placement of flexible plastic tube into the trachea to maintain an open airway. The most widely used route is orotracheal in which orotracheal tube is passed through mouth via vocal cords into the trachea.

Direct laryngoscopy can be done with laryngoscope with patient being sedated, in deep anaesthesia spontaneous ventilation or paralysed, in comatose patient or in patient in shock requiring CPR and even in awake patients.

TECHNIQUE AND POSITIONING FOR DIRECT LARYNGOSCOPY[2]

Intubating trachea of infants and children is different from intubating adults due to anatomical difference in airway as mentioned earlier[4,17]. As paediatric airway dimensions are smaller and there is increased chance of obstruction and trauma to the airway. One of the techniques consists of advancing the laryngoscope blade under constant vision along the surface of the tongue and then placing the tip of the blade directly in the vallecula and then rotates the blade to the right to sweep the tongue to the left and adequately lift the tongue to expose the glottis opening. This avoids trauma to the arytenoid cartilages. Lift the base of the tongue, which in turn lifts the epiglottis, exposing the glottic opening. If this technique is unsuccessful, one may then directly lift the epiglottis with the tip of the blade. Another approach is to insert the Miller blade into the mouth at the right commissure over the lateral bicuspids/incisors (paraglossal approach). The blade is advanced down the right gutter of the mouth aiming the blade tip toward the midline while sweeping the tongue to the left. Once under the epiglottis, the epiglottis is lifted with the tip of the blade, thereby exposing the glottic aperture. By approaching the mouth over the bicuspids/incisors, dental damage is avoided. This is a particularly effective approach for the infant and child with a difficult airway. Whichever approach is used, care must be taken to avoid using the laryngoscope blade as a fulcrum through which pressure is applied to the teeth or alveolar ridge. If there is a substantive risk that pressure will be applied to the teeth, then a plastic tooth guard may be applied. The technique in which laryngoscope blade is advanced into oesophagus and laryngeal visualisation is done during withdrawal of blade is to be avoided as it may result in trauma of arytenoid and aryepiglottic fold[4].

The technique for direct laryngoscopy changes with age. The trachea of older children more than six years age and adults is easily exposed with head elevation of 5-10 cm with pillow placed beneath occiput of the head, displacing the cervical spine anteriorly. Extension of the head at atlanto-occipital position produces the classical sniffing position which aligns the three axes of mouth, oropharynx and the trachea. Once the three axes are aligned they permit direct visualization of laryngeal structures. In infants and younger children it is usually unnecessary to elevate the head because the occiput is comparatively larger in proportion. Head extension at the atlanto - occipital joint alone aligns the airway axis. If the occiput is displaced excessively the view of glottis may actually be hindered. Some may place a rolled towel below the shoulder of the neonates to facilitate intubation, which may be advantageous. In infants and young children straight blade is more suitable than the curved blade because the elevation of tongue is better with straight blade to expose the glottis opening. The type and size of the laryngoscope blade used depends on the age and body mass of the child and the preference of the anaesthetist.

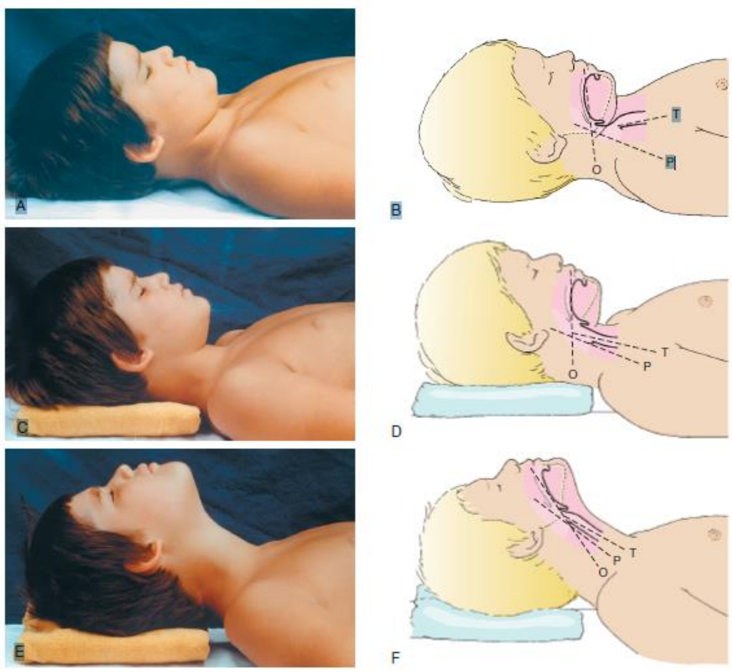

Figure 4- position of direct laryngoscopy

DIFFICULT AIRWAY

A difficult airway is generally defined as a situation in which an experienced clinician experiences difficulty with face mask ventilation, laryngoscopy, or intubation (ASA)[25]. In an emergency setting, this also includes difficulty performing an emergency surgical airway, such as needle cricothyroidotomy[26].

Most children with difficult airway can be identified pre-operatively. Management of children with difficult airway requires prior planning, expertise and practise of advanced techniques. Unexpected difficult intubation is rare in children. For identification of difficult airway history should be taken in detail[26].

Causes of difficult airway[26]:

1. Congenital – hypoplasia of the mandible, Pierre Robin sequence, Treacher Collins syndrome, midfacial hypoplasia, facial clefts, macroglossia, Downs syndrome, laryngeal web.
2. Structural – tracheal stenosis, trauma, aspirated foreign body, post intubation oedema, post burn neck contracture, temporomandibular joint ankylosis.
3. Inflammatory – epiglottitis, croup, laryngeal papillomatosis, retropharyngeal abscess.
4. Neoplastic - cystic hygroma, tumours, meningomyelocele.

ASSESSMENT OF THE AIRWAY-[26]

HISTORY

1. Take proper history of respiratory problems like noisy breathing, stridor, snoring, change of voice, apnoeic spells, sleep apnea, and recurrent croup.
2. Is there any positional variation for the symptoms?
3. Does the child has any feeding problem with regurgitation / aspiration
4. Previous head neck face or cleft palate surgery
5. Previous anaesthesia record of difficult intubation

6. Record of congenital lesion like laryngeal web, haemangioma, laryngomalacia or neck mass?

7. Does he have any associated syndrome?

8. While crying does he opens his mouth widely?

EXAMINATION

General appearance of child, dysmorphic facies, dyspnea, stridor, cyanosis, chest retraction weak cry or drooling saliva should be noted. Head nares and down the airway needs to be examined to rule out neonate-choanal atresia, blocked nasal passages with hypertrophied adenoids or tonsils. Mouth opening and temperomandibular joint mobility should be checked. Mallampati classification and thyromental distance are not validated for small paediatric patients[26]. In uncooperative child mouth opening and jaw mobility are difficult to assess. Loose or protruding teeth, protruding pre maxilla, cleft palate or palatal surgery should be looked for. Tongue size in relation to mandible, neck mass and mobility and thickness of neck should be assessed.

Imaging with X-ray, CT scan or MRI may be useful to diagnose the sight of obstruction. Investigations like arterial blood gas, respiratory function tests, sleep study nasoendoscopy may help further to assess the difficult airway[26].

ENDOTRACHEAL TUBE

The endotracheal tube is a device which is inserted into trachea through larynx to deliver gases to and from the lungs[3].

RESISTANCE IMPOSED BY TRACHEAL TUBE[27]

In spontaneously breathing patients it poses resistance and increases the work of breathing. This factor is important in paediatric patients. The factors which determine resistance by tracheal tube are internal diameter of the tube, length of the tube, tube's configuration and dead space[27].

a. Internal diameter of tube

A thick walled tube offers more resistance than thin walled tube with same outer diameter. Smaller size tubes have greater resistance because of increased ratio of wall thickness to tube diameter. If inner wall is lined by secretions it increases resistance by tube. Passing suction catheter, fibreoptic scope also increases resistance of the endotracheal tube.

b. Length of endotracheal tube

Decreasing length of endotracheal tube decreases the resistance of endotracheal tube. Hence the endotracheal tube must be cut to a proper length to decrease resistance. Decreasing resistance of the tube by decreasing the tube‘s length is much less than that which can be obtained by increasing the internal diameter of the tube.

c. Configuration of the tube

Curves in the tube and connector attached to tube increase the resistance of the tube. Kinking of the tube increases resistance of the tube. If curve of endotracheal tube is gentle resistance offered is less. Swivel connectors also add to the resistance of the tube.

d. Dead spaces

Endotracheal intubation bypasses the natural airways and thus it decreases the dead space .Endotracheal tube and connector imposes mechanical dead space. Long tubes and connectors increase the dead space in paediatric patients for which special low volume paediatric connectors is available.

AVAILABLE VERSIONS OF ENDOTRACHEAL TUBE[27,28]-

Now a days, most of the disposable endotracheal tubes are made up of polyvinyl chloride. It is biocompatible, tends to conform to patients upper airway, less likely to kink but are stiff enough for intubation and comparatively cheaper. These tubes have smooth surface through which bronchoscope and suction catheter can pass easily. Transparency of these tubes allows seeing if secretions or aspirated material is there in the lumen of tube. Tubes made from silicone are expensive but they can be sterilized and reused. Endotracheal tubes with micro thin walled high volume low pressure polyurethane cuffs are also available. They have short bevel hence less chance of endotracheal intubation. There is no murphy’s eye.

TUBE DESIGN[27]-

International standard has recommendations for tracheal tube which have recommendation for material of tube, internal diameter, length of tube, radius of curvature, inflation system, cuff, markings, labelling and packaging[27,29].

i. The internal and external wall of tracheal tube should be circular.
ii. Machine end or proximal end receives the connector and projects from the patient. Tube can be cut short to decrease the dead space at this end.
iii. Patient end or distal end is inserted into the trachea.
iv. Endotracheal tube have slanted portion at patient end called bevel which faces to left when tube is viewed from its concave aspect.
v. Some tubes have hole opposite to bevel called murphy's eye which provides alternate pathway for gas flow if bevel becomes occluded.
vi. Tubes which lacks murphy's eye are called Magill type tube.
vii. Radiopaque marker is placed along entire length of tube to determine tube position after intubation.

UNCUFFED ENDOTRACHEAL TUBE

For the same patient selection of 0.5 mm larger size than cuffed tube reduces the resistance offered by tube[23]. In children increase in even 0.5 mm matters a lot. Less blockage of tube with secretions is observed as compared to cuffed tubes due to larger tube size. Suction catheter and fibreoptic scope can be passed through the lumen easily due to larger tube size[27]. Uncuffed endotracheal tubes are cheaper and so reasonable for small duration surgery if cuffed tubes are not indicated[27]. No cuff pressure monitor required.

CUFFED (CETT) VERSUS UNCUFFED TUBES (UETT)-

Earlier uncuffed tubes were routinely used for children less than 6 years of age because uncuffed tube exerts minimal pressure with air leak on cricoid cartilage and thus there is less risk of post intubation oedema[2]. In recent years cuffed endotracheal tubes have been used more frequently in smaller children. Some studies show that there is not much difference between cuffed and uncuffed tube for post intubation oedema[30,31]. Cuffed tubes perform as well or better than uncuffed tubes in children undergoing anaesthesia with muscle relaxant, noting fewer required intubation attempts and no difference in the incidence of postoperative croup[5,32,33]. Bharadwaj et al (2013) concluded that CETTs offer a large number of advantages for their routine use in paediatric patients[34]. Their use requires selection of correct-sized tracheal tube, its correct placement, and cuff pressure monitoring during the conduct of anaesthesia[34]. The increased cost of CETTS is compensated by the decrease in rate of tracheal re-intubation with different sizes of UETTs as well as a reduction in consumption of halogenated agents by ability to use low-flow anaesthesia[34].

There is variability in outer diameter of tubes of different manufacturers even if internal diameter remains same. For selection of cuffed tube size 0.5mm to 1mm smaller size from uncuffed tube for same age is used[35]. Resistance to breathing is determined by internal diameter of tube but mucosal injury is related to external diameter[24,35]. Uncuffed tubes have larger diameter and therefore less resistance for spontaneous breathing and mechanical ventilation[27]. There is a lower chance of occlusion of tube with secretions[27]. Since there is no cuff there is no concern about ridges of the cuff and tip to cuff border distance. There is no requirement for cuff pressure monitoring as there is no cuff.

CUFFED TUBE

Indications [27,36]-

- cuffed tubes are indicated in patients with high risk of aspiration,
- pre-existing impaired pulmonary compliance specially if they are undergoing abdominal or chest surgery,
- patients undergoing cardiopulmonary bypass
- Patients who require precisely controlled mechanical ventilation.

Advantage[2] [27,36,37] –

- Require fewer repeat laryngoscopies and intubations
- They cause less contamination of the atmosphere as the cuff seals the gases from escaping
- Need lower gas flows.
- Provide better protection against aspiration.
- They provide improved accuracy of monitoring end tidal gases, tidal volume, lung compliance and oxygen consumption.

Disadvantage [27]

- CETT requires choosing slightly smaller tube which makes it difficult to pass suction catheter and tube obstruction is more likely.
- Smaller size increases resistance of tube.

Poiseulle law governs resistance to laminar flow through a tube, which states that resistance is proportional to the length of the tube and inversely proportional to fourth power of radius[38].

Small amount of inflated air may lead to rapid increase in cuff pressure and over inflation of cuff will result in excessive pressure against the mucosa. CETT may be used to occlude trachea oesophageal fistula[27].

Microcuff endotracheal tube -

To overcome shortcoming of paediatric cuffed tube microcuff endotracheal tube was designed[28]. It has high column low pressure cuff which is placed more distally along the shaft of endotracheal tube to better accommodate paediatric anatomy[28,39]. Ultrathin polyurethane cuff of 10 micron allows tracheal sealing at low pressure and provides uniform contact with minimal cuff fold formation. There is no murphy's eye which allows more distal placement of the cuff[28,39]. It reduces the pressure which is applied to cricoid and adjoining mucosa. Position of cuff has lesser risk of endobronchial intubation or intralaryngeal cuff position[39]. Black mark at distal end serves as depth marker of the tube. Only issue with this tube is cost (3 times the cost of regular ETT)[39]. As the tube warms it becomes soft as a result kinking is a concern for smaller sized Microcuff tubes. Studies show microcuff tubes show lower sealing pressures than conventional cuff [27]. Some studies have shown the incidence of re-intubation is 1.6% and postintubation croup as 0.4%[2]. Safety and efficacy of these tubes need to be established in larger cohort study.

SIZE OF ETT-

Appropriate size tube can be estimated depending upon age , height and weight of patient. ETT of one size below and above should be available as the anatomical variations are present. After intubation if there is no leak around tube at 20 -25 cm H_2O peak inflation pressure, the ETT should be changed to next half smaller size[27]. An air leak at this pressure is recommended as it is believed to approximate capillary pressure of the tracheal mucosa. If lateral wall pressure exceeds this amount, ischemic damage to the subglottic mucosa may occur[27].

There is considerable variation in subglottic size in children and in the external diameters of paediatric tracheal tubes[27].

Age based formula-

- Penlington’s formula

For children below 6 years[8]: size of ETT = age in years/3 + 3.5

For children older than 6 years[40]: size of ETT= age in years/4 + 4.5

- Cole’s formula[4] : Size of ETT = age in years/4 + 4
- Khine formula[5] : size of ETT = age / 4 + 3

- Size of ETT = 3 mm for those 3 months of age and younger

  Size of ETT = 3.5 mm for those from 3 to 9 months of age

  Size of ETT = (age in years + 16)/4 over 9 months of age [7]

- Based on body length [41] :

  Size of ETT = height (cm) / 30 + 2

- Based on body weight[42] :

  Size of ETT = weight (kg) / 10 + 3.5

- Motoyama's formula[23] for cuffed ETT for > 2 years = age / 4 + 3.5

- Choosing a tube whose external diameter is the same width as the distal phalanx of the little or index finger[43]. (Less accurate method but useful when the child's age is unknown)

- Based on age, height and weight [44]

  Size of ETT = 2.44 + (age × 0.1) + (height in cm × 0.02) + (weight in kg × 0.016)

LENGTH OF ETT

There is a correlation between airway length and body height[27,45]. For patients whose body lengths lie outside the normal range, the tube can be placed alongside the patient's face and neck[27]. The tip of the tube is aligned to the suprasternal notch, and the tube is aligned to conform to the position of a nasal or oral tracheal tube. The place on the tube at which the tube intersects with the teeth or gums (oral intubation) or the nares (nasal intubation) is noted, and the tube is secured at that point[27].

In children, length of the trachea (vocal cords to carina) in neonates and children up to 1 year of age varies from 5 to 9 cm. In most infants 3 months to 1 year of age, if the 10-cm mark of the ETT is placed at the alveolar ridge, the tip of the tube rests above the carina. In preterm and full-term infants, the distance is less. In children 2 years old, 12 cm is usually appropriate. An easy way to remember these lengths is **10** for a new born, **11** for a 1-year old and **12** for a 2-year old.

The margin of safety in children is less than in adults. A number of formulas have been developed, including the following:

Oral Intubation[27]-

- Length in centimetres = age/2 + 12 cm
- Length in centimetres = weight in kilograms/5 + 12 cm.
- Length in centimetres = height in centimetres/10 + 5 cm
- Length in centimetres = weight + 6

- Rule of 7-8-9: infants weighing 1 kg are intubated to a depth of 7 cm at the lips, 2-kg infants to a depth of 8 cm, and 3-kg infants to a length of 9 cm[46].
- Equations based on the crown-rump and crown-heel length have been developed[47] .
- Many tubes have lines or rings to help position the tube with respect to the vocal cords and the distal portion of some paediatric tubes have depth markers[48]. Guide (depth) marks vary in their position relative to the cuff and tip of the tube[49].

LEAK

A leak may make it difficult to maintain adequate ventilation, fail to protect against aspiration, and increase the difficulty of surgery involving the oral cavity [50].

During insertion, the cuff, inflation tube, or the tube itself may be torn by a tooth, turbinate, implant, laryngoscope blade, forceps, or stylet [27,51]. A problem with the inflation system or the syringe used to inflate the cuff may make it impossible to inflate the cuff [27,52]. A defect in the tube or eccentric cuff inflation can cause a leak. [27 53] The tracheal tube connector may be the source of a leak. [27,54]

Protrusion of the cuff above the vocal cords can result in a leak despite a large amount of air being injected into the cuff [55]. The cuff can develop a leak while the tube is in place[56]. Application of local anaesthetic spray has been associated with cuff leaks.[57] The cuff or other parts of the tube may be damaged during cannulation of the internal jugular or subclavian veins, during percutaneous dilatational tracheostomy or by other nearby procedures[27,58]. A laser beam can perforate the cuff[59]. A tube may be damaged by biting[60]. Chewing gum attached to a cuff can cause an unsatisfactory seal[61].

If a leak becomes evident after a gastric tube or other device has been placed, the possibility that that device has passed into the trachea alongside the tracheal tube instead of into the oesophagus should be considered[27].

When a leak is present, laryngoscopy should be performed. If the cuff is above the vocal cords, it should be deflated and the tube advanced before the cuff is reinflated[27]. Consideration should be given to using a tube exchanger or fiberscope during this procedure, especially if intubation was difficult[27].

If the problem is in the inflation system, it may be possible to repair the damage, or the leak can be bypassed by inserting a stopcock, small catheter, or a needle into the line below the defect[27]. It may be possible to seal a cut in the tube itself by using glue[62]. Temporary approximation of the cut edges and circumferential packing may be helpful[63].

If the cuff is leaking, several alternatives are available[27]:

- Pharyngeal packing should be used to control the leak. It may be necessary to increase the fresh gas flow to compensate for the leak.

- Cuff should be filled up with a mixture of lidocaine and saline or use a saline infusion.
- Mechanism should be attached for maintaining a continuous gas infusion into the inflation tube. Methods described include tubing connected to an air-filled plastic container to which constant external pressure is applied, a flowmeter, and a system for maintaining intraocular pressure
- Supraglottic device such as an LMA should be placed over the tube to seal the proximal end.
- Replace the tracheal tube. If this course of action is selected, consideration should be given to using a tube exchanger.

When a damaged tube is removed, it should be carefully examined to make certain that there are no missing portions.

METHODS TO CHECK THE POSITION OF ETT-[27]

i. Direct visualization as the tip of the tube passes through glottis
ii. Wave form capnography as emerged as gold standard for confirmation of tube placement within trachea, but does not rules out endobronchial intubation
iii. Observation of symmetry of chest expansion
iv. Auscultation for equality of breath sounds in axilla and apices. also auscultate over stomach
v. Humidity on walls of tracheal tube during expiration confirms endotracheal intubation. It may not be applicable in younger infants

vi. Fibreoptic bronchoscope

vii. Oesophageal detector device

viii. Chest XRAY to assess the distal tip of endotracheal tube

COMPLICATIONSOF ENDOTRACHEAL INTUBATION [2,3,27]-

Endotracheal intubation is associated with complication, some of which are life threatening. One should be aware of the complications and try to prevent and manage them whenever they arise. Complications are more common in infants and smaller children as they have a smaller larynx and more prone to airway oedema. Patient with difficult airway are more prone to injury and hypoxic events. Syndromic patients may pose difficulty during intubation. Complication occur more during emergency situation.

Complications happen during various stages of intubation.

Complications at the time of intubation-[3]

i. Failed intubation- Most dreaded is cannot ventilate cannot intubate (CVCI) situation which may cause failed oxygenation which may lead to hypoxic brain damage and death. Surgical airway is the preferred method in CVCI. If mask ventilation is possible laryngeal mask airway may be lifesaving. Jet ventilation may be rescuer but risk of barotrauma is there.

ii. Bronchial intubation and esophageal intubation- The un-intubated lung does not contribute to gas exchange which may lead to shunt and hypoxia. The intubated lung may be hyperinflated and barotrauma may result. Using standard formula for length of tube may be helpful. If endobronchial intubation is discovered the endotracheal tube should be pulled by a few centimetres.

iii. Trauma to lips, teeth, tongue and nose

iv. Laryngospasm- It may occur during attempted intubation in lighter planes of anaesthesia. It may result in hypoxia, inability to ventilate the lungs and hypoxia. It can be corrected by giving Larson's maneuver, deepening plane of anaesthesia or giving a muscle relaxant.

v. Bronchospasm- The presence of ETT in trachea may produce bronchoconstriction. It may be severe in patients with lighter anaesthesia and reactive airways. It may be blunted by prior administration of anticholinergics, steroids, beta 2 agonist, topical or iv lignocaine and narcotics. It should be ensured that it is not due to tube obstruction, tension pneumothorax or heart failure.

vi. Noxious autonomic reflexes- Laryngoscopy and intubation causes increase in the level of catecholamines which causes tachycardia, hypertension, myocardial ischaemia , depression of myocardial contractility, ventricular arrhythmias and intracranial hypertension. Increase in duration of laryngoscopy may result in increased response.

To obtund these reflexes one may use fentanyl 3-4 microgram/kg, lignocaine 1.5 mg/kg, beta blocker like esmolol.

vii. Airway trauma - Lips, teeth, tongue, pharynx, larynx, trachea, and bronchi may be injured during laryngoscopy and intubation. Nasal, retropharyngeal, pharyngeal, uvular, laryngeal, tracheal, oesophageal and bronchial trauma may occur while intubation.

viii. Airway perforation - Oesophagus, trachea and bronchi may get perforated during intubation, more so when there are repeated attempts in case of difficult airway. Subcutaneous emphysema may occur after intubation. Neck pain, dysphagia, erythema and oedema may occur. Mediastinitis may occur, which may lead to sepsis and even death. Overinflation of tube cuff may lead to tracheal mucosal injury and even laceration. Use of stylet may increase the chance of injury. When injury occurs, thorough search may be made using bronchoscope and remedial measures should be taken.

ix. Cord avulsions, fractures and dislocation of arytenoids.

x. Corneal abrasion, occlusion of central retinal artery of retina and blindness. Spinal cord and vertebral column injury may occur during intubation. Head may be stabilised within line manual stabilization if cervical spine injury is suspected.

xi. Raised intracranial pressure and raised intraocular pressure

Complication when ETT is in place[3]-

i. Tension pneumothorax - It may occur due to airway perforation during intubation or barotrauma during IPPV. It may lead to severe hypoxia and hypotension. An immediate X-ray confirms the diagnosis. If pneumothorax is causing cardiorespiratory compromise, it should be immediately decompressed using wide bore cannula in second intercostal space midclavicular line.

ii. Disconnection and dislodgement of ETT- Extension of the neck causes cephalad movement of ETT, excessive movement of head during surgery, loose fixation of the tube, heavy connection producing drag on ETT and on circuit, inaccessible tube during head neck surgery and during neurosurgery. If airway pressure and capnography are monitored continuously it can be detected early.

iii. Incomplete seal- This may be due to smaller tube size, leak in the cuff and leak in inflation valve, incorrect cuff position or cuff above vocal cords. This may lead to inadequate ventilation and aspiration of gastric content. As per the case change the tube or reposition the cuff.

iv. Obstruction of the tube- It may be caused by kinking of the tube biting of the tube, obstruction by secretions and blood clot, impaction of tube against tracheal wall. It may manifest as high airway pressure, wheeze and increased resistance to ventilation. When obstruction of ETT is diagnosed, visual inspection and passage of suction catheter should be carried out to rule out the given possibilities. If necessary, ETT should be changed.

v. Aspiration of gastric contents - Head up position, accumulation of secretions above tube, use of uncuffed tube or cuff leakage increases the chances of aspiration.

vi. Fire during laser surgery.

Complications during extubation-[3]

i. There may be difficulty in extubation if cuff fails to deflate. The cuff can be punctured through the cricothyroid membrane.

ii. Tube may be sutured to trachea or bronchus during surgery (pneumonectomy) or to adjoining structures during head and neck surgery. If tube is not coming out easily, avoid vigorous extubation attempts. Direct or fibreoptic examination should be done.

iii. During extubation airway obstruction and laryngospasm can occur. Patients intubated for more than eight hours can have impaired airway protection for 4-8 hours.

iv. Laryngeal oedema - Cricoid cartilage is the narrowest and non-expandable part of paediatric airway. Hence subglottic oedema is more common in children. Oedema may also be present in uvular, supraglottic and vocal cords region and clinically manifests as inspiratory stridor. If this stridor diminishes further it may represent total airway obstruction. Using larger size endotracheal tube (no leak for >25 cm water), trauma during laryngoscopy and intubation, coughing or bucking on tube, excessive neck manipulation during surgery, recent respiratory infection, surgery longer than 4 hours may contribute to the formation of laryngeal oedema. Treatment includes humidified oxygen, racemic epinephrine and dexamethasone. The incidence of post extubation croup is 0.1% to 1% in children. The use of dexamethasone is unproven; some studies advocate its use while others do not. If obstruction is severe and persistent reintubation must be considered.

Complication after extubation-[3,27]

i. Sore throat - Sore throat is a minor side effect which usually resolves in 72 hours. Incidence is influenced by area of cuff in contact with trachea. Cuff with higher cuff trachea interface result in higher incidence of sore throat. Sore throat is also related to intracuff pressure. Use of larger size ETT may also increase the incidence of sore throat.

ii. Laryngeal oedema

iii. Hoarseness- It is minor side effect which resolves spontaneously, should be investigated if persistent.

iv. Nerve injury - Difficult intubation may lead to compression injury to lingual nerve leading to loss of sensation.

v. Aspiration of oral or gastric contents

vi. Tongue injury- Prolonged compression by large ETT or airway may lead to ischemia and venous congestion resulting in macroglossia. Massive tongue swelling may also be caused by obstruction of submandibular duct by ETT.

vii. Superficial laryngeal ulcers- Result even after short period of intubation and incidence increases with longer time of intubation. The ulcers correspond to the convex curve of ETT, tip and cuff. Hence found on posterior aspect of larynx and anterior, lateral aspect of trachea. Superficial ulcers heal rapidly. Deep ulcers may take time to heal and result in scarring.

viii. Laryngeal granuloma - Glottis and subglottic granulation tissue. It is formed from granulation tissue over the ulcer. Patient maybe asymptomatic or may have hoarseness, pain and discomfort in throat. It may also lead to chronic cough and hemoptysis. Granulomas heal spontaneously and patients need strict voice rest. If patients have pedunculated lesion, or if they develop respiratory obstruction only then surgical intervention is required.

ix. Vocal cord paralysis- Recurrent laryngeal nerve gives anterior branch which enters between cricoid and thyroid cartilage supplying the intrinsic muscles of larynx. An inflated cuff at this location can compress the nerve overlying thyroid cartilage. Unilateral injury to recurrent laryngeal nerve prevents abduction of cords; hence the cords remain in adducted position. This usually presents as hoarseness in post-operative period. Bilateral injury may result in airway compromise and require immediate reintubation or tracheostomy. Injury to the nerve can be prevented by avoiding overinflation of cuff and avoiding excessive tube migration during anaesthesia. Usually it recovers spontaneously in days to months.

x. Laryngo-tracheal membrane- It is rare but fatal complication which may lead to respiratory obstruction, with symptoms occurring after 24 to 72 hours after extubation, direct laryngoscopy and bronchoscopy is done for diagnosis and managed by removal through suction.

xi. Tracheal stenosis- Overinflation of cuff produces pressure against the lateral wall of trachea leading to ischemia and necrosis when the lateral pressure on trachea exceed capillary perfusion pressure of 25 mm Hg. Continuous ischemia may be followed by partial or complete destruction of tracheal rings and loss of structural integrity of affected tracheal segment. Healing of damaged tracheal segment may lead to tight fibrous stricture which may cause stenosis. It can be prevented by using high volume low pressure cuff with the cuff pressure not exceeding 25 -30 mm Hg. Cuff pressure manometer should be used intraoperatively to prevent mucosal ischemia.

xii. Tracheomalacia, tracheo-oesophageal fistula, tracheo-innominate fistula are complications of tracheostomy.

ULTRASONOGRAPHY[14,64]-

Ultrasound uses sound waves for imaging. Sound is mechanical energy which is transmitted through a medium by vibration of molecules. The molecules oscillate in a line which is in same direction as propagated wave[64].

Clinical ultrasound waves are transmitted through soft tissues of body at average speed of 1540 m/s. Speed for bone is 4080 m/s. For medical imaging 2 -15 megahertz frequency is used. Ultrasound machine consists of probe, computer system and a monitor. The ultrasound machine works on the principle of piezoelectric effect[64].

Some substances change shape when electric charge is applied across them and have the converse effect that when pressure is applied they change shape and electric charge is generated. This is known as piezoelectric effect. Such piezoelectric material forms the transducers of USG probe. It allows acting as both sound transmitter and receiver. Electric charge is applied to transducer and ultrasound signal is produced. This sound wave propagates into the tissues and is reflected back. The reflected wave returns to the probe and generates electrical signal, which is processed to produce an image. The electrical energy is transmitted to computer system and images are displayed on monitor by Fourier transformation[64]. The frequency of ultrasound probe must be carefully selected to provide proper balance between image detail and depth of penetration. Higher the ultrasound frequency, the lower the pulse duration which leads to better axial resolution. Greater resolution is produced by high frequency probe emitting wave at frequency of five to thirteen megahertz. They do not penetrate deeply into tissues. Resolution is far less with low frequency probes with frequency between 2-5 megahertz, which can penetrate tissue deeply (up to 30 cm depth). Reflection, refraction, scatter, absorption and transmission of sound occurs as it passes through soft tissue structures, allowing characterization of shape and internal architecture of that particular structure and those behind it. The reflection of sound is marked at interfaces between tissues of different acoustic impedance. Fluids and soft tissues transmit medical ultrasound well but air and bone does not transmit them well. Compact structures like bone or calculus obstruct the transmission of sound waves producing bright areas called as **hyperechoic**. Muscles and fat partially transmit the sound waves which appear in grey shades called **hypoechoic**. Fluid medium results in near complete transmission of sound waves which appear black on monitor and called **anechoic**[64]. This principle of ultrasound imaging is known as acoustic impedance of tissues. At soft tissue interface with bone or air the impedance difference is the greatest. Air is poor transmitter of ultrasound. At tissue air interface ultrasound waves produce strong reflection, beyond which they are called reverberation artefacts which appear as multiple parallel white lines with dirty shadowing on the screen. The lumen filled with air prevents the visibility of deeper structures.

Transducer selection - Different transducers are available for different structures of imaging. For deeper structures like abdomen and obstetrics imaging curvilinear probe with frequency of 3-5 MHz is used. For imaging of superficial structures like neck, breast, scrotum, musculoskeletal system linear probes with frequency of 7-15 MHz are used. For transrectal and transvaginal examination probe with frequency of 5-9 MHz are used. For echocardiography sector probes with frequency 3-6 MHz are used. High frequency linear probes are useful for assessment of the imaging of airway [64].

ULTRASOUND OF THE AIRWAY[14,65]-

Ultrasound imaging of airway helps in rapid assessment of airway in operating room, intensive care and emergency department that is not evident by clinical examination alone[14]. Scope of ultrasound imaging of airway for guidance of airway assessment is growing rapidly.

Accurate interpretation of US images requires a basic understanding of the physical principles of ultrasound image generation, transducer selection, orientation and knowledge of anatomy of airway relevant to US imaging is important to evaluate anatomy of the airway[14].

Appearance of various medium of airway on ultrasound imaging[14,65,66]-

- Bony structures like sternum, ramus of mandible, mentum and hyoid bone appear as bright hyperechoic linear structure with hypoechoic acoustic shadow below.
- Cartilaginous structures like thyroid and cricoid cartilage appear homogeneously hypoechoic.
- Muscle and connective tissue appear as hypoechoic structure with heterogenous striated appearance.
- Fat and glandular structures appear as homogeneous and more hyperechoic in comparison to adjacent soft tissues.
- Air is poor transmitter of ultrasound and appears as hyperechoic artifact and it does not allow visualization of deeper structure.
- Air – mucosa interface appear as bright hyperechoic linear structure. During ultrasound scanning of the airway, the oral and nasal cavities, pharynx, larynx and trachea are filled with air. The detailed description of various airway structure on ultrasound imaging is given below;
- **Tongue and floor of mouth**: Tongue is visualized deeper to muscles of floor of mouth. Using curvilinear probe in submandibular region, on transverse view the tongue appears as curvilinear hyperechoic structure. The muscles of tongue namely myelohyoid, geniohyoid and genioglossus appear as hypoechoic structure. Lingual septum appears as linear hyperechoic structure in midline. On sagittal view, geniohyoid and

myelohyoid appear as linear hypoechoic bands extending between mandible and hyoid. Genioglossus and hyoglossus appear in fan like fashion .The dorsal surface of tongue appear as curvilinear hyperechoic structure due to air mucosal interface.

- **Epiglottis:** On transverse view, with cephalad and caudal movement of transducer through thyrohyoid membrane, epiglottis appears as hypoechoic curvilinear structure (inverted C). The identification of epiglottis in real time is facilitated by tongue protrusion and swallowing movements and appears as discrete mobile structure inferior to base of tongue. Its anterior border is delineated by hyperechoic pre-epiglottic space and its posterior border is marked by bright linear air mucosal interface. On parasagittal view, due to acoustic shadowing by hyoid bone it becomes difficult to visualize the epiglottis.

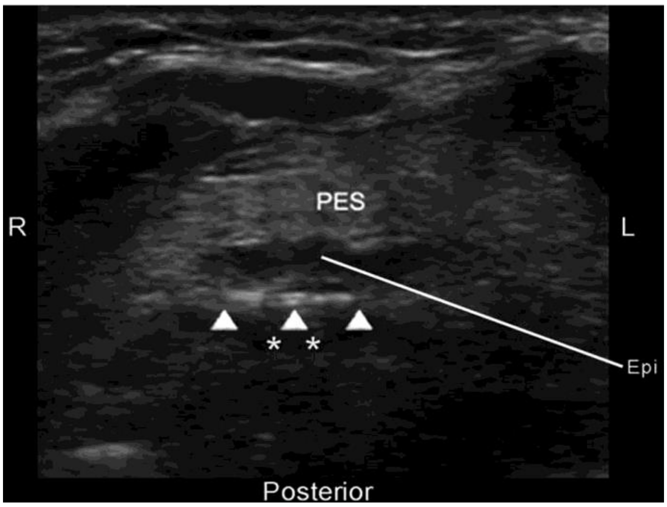

Figure 5- USG image in midline TS showing Epiglottis

- **Hyoid bone:** On transverse view, hyoid appears as superficial, hyperechoic inverted U shaped structure with posterior acoustic shadowing. On sagittal and parasagittal view hyoid appears as narrow hyperechoic structure that casts an acoustic shadow.

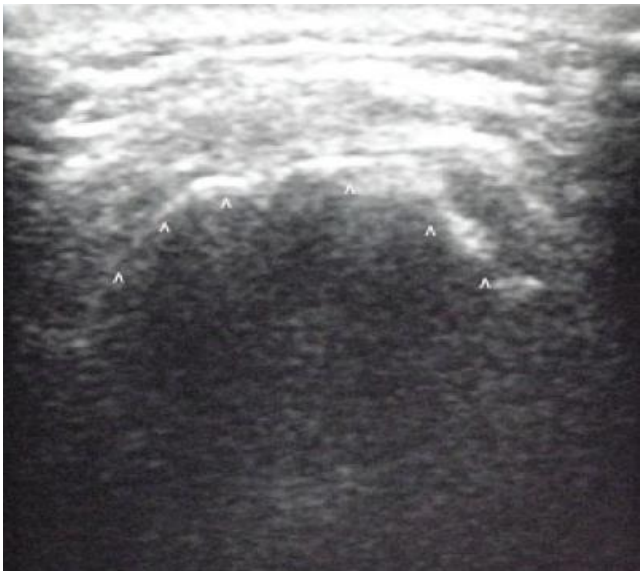

Figure 6 – USG image in midline TS showing hyoid bone

- **Thyrohyoid membrane:** In transverse and parasagittal view, it provides sonographic window for visualization of epiglottis. It is difficult to identify the superior laryngeal nerves.
- **Vocal cords:** In transverse view, vocal cords can be seen through thyroid cartilage window by sliding the transducer in cephalocaudal direction over thyroid cartilage. True vocal cords appear as hypoechoic triangular structure, vocalis muscle appear as isosceles triangle. Medially they are lined by hyperechoic vocal ligament. The false vocal cords lie cephalad to true vocal cords and are hyperechoic in appearance. The true vocal cords move towards midline during phonation whereas the false vocal cords remain immobile.

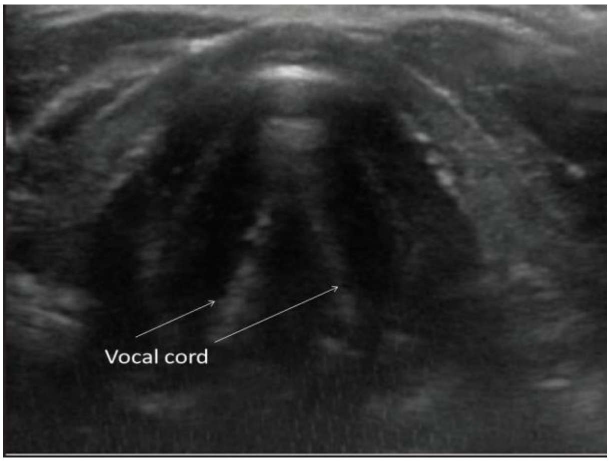

Figure 7 – USG image in midline TS showing vocal cords

- **Cricoid cartilage and cricothyroid membrane:** On transverse view the cricoid cartilage has an arch like appearance. The posterior surface of anterior wall is delineated by bright air mucosa interface as well as reverberation artifact called comet tail artifacts from intraluminal air. On parasagittal view cricoid cartilage has round hypoechoic appearance. On sagittal and parasagittal view the cricothyroid membrane appear as hyperechoic band linking hypoechoic thyroid and cricoid cartilage.

Trachea and adjoining structures: On transverse view, they appear as hypoechoic inverted U highlighted by linear hyperechoic air mucosa interface and reverberation artifact posteriorly. On sagittal and parasagittal view they appear hypoechoic and resemble "string of beads". In transverse view at level of suprasternal notch, two lobes of thyroid with isthmus can be seen anterolateral to trachea. The normal thyroid gland appears homogeneously hyperechoic than adjacent strap muscles. In transverse view, the oesophagus can be visualized at level of suprasternal notch posterolateral to trachea. Swallowing helps to see peristaltic movement and identification of esophageal lumen.

CLINICAL APPLICATION OF USG FOR AIRWAY

Kristensen et al described the expanding role of ultrasonography in clinical decision making, management of the upper and lower airways[11]. They have given an overview of how to obtain bedside real-time ultrasonography of the upper and lower airway and of other organs crucial for airway management and its practical application[11].

Benefits in airway diagnostics and management[11,14,16]-

- The tracheal structures can be identified and measured by ultrasonography, even when unidentifiable by palpation.
- Ultrasonography is the primary diagnostic approach in suspicion of intraoperative pneumothorax.
- Point-of-care ultrasonography of the airways has a steep learning curve[11].
- Lung ultrasonography helps in diagnosis of interstitial syndrome, lung consolidation, atelectasis and effusion.
- Ultrasound is safe, quick, repeatable, portable and widely available and it gives real time dynamic images.it is very helpful even in emergency setting for evaluating airway[11,14].

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- Prediction of difficult laryngoscopy: Ultrasound assessment of base of tongue and thickness of soft tissue of anterior neck had a better correlation with difficult laryngoscopy (Cormack-Lehane grade 3,4)[67]. In obese patients the ultrasound assessment of distance of skin to anterior aspect of trachea with measurement made at level of vocal cords and suprasternal notch significantly correlated with difficult laryngoscopy in spite of giving optimum laryngeal manipulation. The hyomental distance ratio (distance between upper border of hyoid bone and lower border of mentum with head in neutral position to head hyperextended) is useful predictor of difficult laryngoscopy[11,68]. Hyomental ratio greater than 1.1 had easy laryngoscopy and ratio < 1.1 had difficult laryngoscopy. Evidence is still insufficient to recommend these as standard screening techniques.
- Evaluation of pathology interfering with airway: Laryngeal cyst, laryngeal stenosis, subglottic haemangioma and respiratory papillomatosis can be identified using sonography. Zenker's diverticulum which can cause regurgitation and aspiration can also be identified with ultrasound. Airway malignancy can also be assessed. Prenatal ultrasound can be useful for identifying fetal airway abnormality like cervical teratoma and lymphatic malformation and expectant management can be planned. Submandibular and parotid swelling can also be identified.

- Assessment of obstructive sleep apnea: Ultrasound measurement of tongue width and lateral pharyngeal wall correlate with sleep related breathing disorder[11,69].
- Evaluate prandial status: Ultrasound has good reliability in identifying a full stomach but less reliable in identifying empty stomach. It can detect and quantify stomach contents. The cross sectional area of gastric antrum can detect fluid up to 300 ml when patient is placed in right lateral decubitus position. Prior to endotracheal intubation in emergency setting ultrasound setting can detect and quantify contents in stomach. It is also possible to detect nature of gastric fluid whether clear fluid, thick or solid.
- Prediction of appropriate diameter of endotracheal, endobronchial and tracheostomy tube: Ultrasound can reliably measure subglottic diameter showing good correlation with gold standard of MRI. It can be used for guiding selection of double lumen tube by measuring left main stem bronchus diameter. Size and shape of the replacement tracheostomy tube can be determined by measuring the width of trachea and distance of skin to trachea by placing the probe just superior to stoma.
- Localization of trachea: Preoperative localization of trachea with ultrasound is very helpful in patients with obesity, short thick neck, prior irradiation, neck surgery, neck masses or thoracic pathology causing deviation of trachea. It is also useful in cases of awake tracheostomy

because of predicted difficult mask ventilation or difficult tracheal intubation.

- Localization of cricothyroid membrane[11,70]. By conventional methods identification of cricoid membrane is correct only in 30% cases. Ultrasound allows faster and reliable identification of cricothyroid membrane and trachea useful in elective transtracheal cannulation and emergency cricothyrotomy. The cricothyroid membrane can be localized in advance of trial of difficult intubation; In case airway is lost emergency cricothyrotomy can be done.
- Airway related nerve blocks[11]: ultrasound helps in identifying and blocking superior laryngeal nerve for preparation of awake intubation when landmarks are difficult to identify. The greater horn of hyoid and superior laryngeal artery can be identified and local anaesthetic can be injected in between. It is difficult to visualize superior laryngeal nerve in some patients.
- Confirmation of endotracheal tube placement[11,71]: Ultrasound confirms if endotracheal tube enters trachea or esophagus directly by real time scan of anterior neck during intubation or indirectly by looking for ventilation at the pleura. Accidental oesophageal intubation can be recognized immediately when real time ultrasound scan is done, detected even before ventilation is initiated. It has advantage over capnography that it can be used in very low cardiac output state. Checking for ventilation at the pleural level distinguishes between tracheal and endobronchial

intubation. Colour Doppler can be used as a supplement to observe lung sliding and confirming ventilation. To distinguish between tracheal and endobronchial intubation, lung must be scanned bilaterally. If lung sliding is present on one side and lung pulse on the other suggests that tip of tube is present on the main stem bronchus where lung sliding is present.in such cases tube should be withdrawn till lung sliding is present bilaterally. Ultrasound shows high sensitivity in detecting oesophageal versus endotracheal intubation but shows lower sensitivity in detecting endobronchial intubation .Ultrasound also helps in confirming position of double lumen tube .if there is neither lung sliding nor lung pulsation pneumothorax should be suspected.

- Confirming of laryngeal mask placement[72]: Ultrasonography helps in detecting correct placement of laryngeal mask airway and in assessing adequacy of laryngeal seal and pulmonary ventilation.
- Tracheostomy[73]: When surface landmarks are impalpable accurate localisation of trachea can be done by using ultrasound. It is particularly helpful in children to prevent subglottic damage in cricoid cartilage and damage to first tracheal ring.
- Percutaneous dilatational tracheostomy[74]: Real time ultrasound helps in localizing the trachea, visualization of anterior tracheal wall, pretracheal tissue including blood vessels and selection of proper intercartilaginous space for placement of tracheostomy tube . It helps to cannulate the trachea without perforating the posterior tracheal wall. Ultrasound helps

to avoid major blood vessels like arch of aorta and innominate vessel while performing tracheostomy.

- Diagnose lung pathology[11]: Ultrasound helps to diagnose lung pathology like pneumothorax, interstitial syndrome, focal B lines, lung consolidation, atelectasis and pleural effusion. Ultrasound has a very good sensitivity and specificity in diagnosing pneumothorax as compared to chest X ray. Four characteristic ultrasound signs have been described to diagnose and exclude pneumothorax - lung sliding, B lines, lung pulse and lung point. Ultrasound can also be used to quantify small and large pneumothorax. Interstitial syndrome has a very high sensitivity but less specificity for diagnosing cardiogenic pulmonary oedema. B lines are dynamic in diagnosing cardiogenic pulmonary oedema. In compression atelectasis, lung tissue is seen floating in pleural effusion called “jelly fish sign”. Pleural effusion will appear as a dark anechoic area between parietal and visceral pleura .hence ultrasound is used in assessment and subsequent treatment of pleural effusion. Thoracocentesis can be done under ultrasound guidance. It can serve as a guide to time the removal of chest tube by quantification of residual pneumothorax size.
- Diagnosis of pulmonary embolism[75]: Ultrasound shows a sensitivity of 80 % and specificity of 93% in diagnosing pulmonary embolism.
- Obstructive pulmonary disease: Patients with COPD and asthma have normal appearance of lung during exacerbations but rules out complications associated with these diseases.

- Used for extended focused assessment with sonography and trauma(EFAST)
- Confirmation of gastric tube placement with ultrasound has 97% sensitivity: USG can be used to confirm placement of Sengstaken – Blackmore tube applied for severe oesophageal variceal bleeding[76].
- Prediction of successful extubation[77]: Patients with post extubation stridor had narrow column of airway when transducer was placed on transverse view on cricothyroid membrane of larynx. Ultrasound also helps to evaluate the breathing force of intubated patients receiving mechanical ventilation.by placing the probe on anterior axillary line on right and posterior axillary line on left for measurement of liver and spleen displacement in craniocaudal aspect respectively. The displacement of liver and spleen reflect the global function of respiratory muscle and is a good parameter to assess respiratory muscle endurance and to predict successful extubation.

FUTURE ASPECTS

- Endoscopic high frequency ultrasound of larynx gives useful information about pathology of larynx. Technique involves high frequency probe with thin catheter with rotating mirror to spread the ultrasound ray producing 360 degree image rectilinear to the catheter.

- Ultrasound imaging of trauma victims for pneumothorax and haemothorax in FAST protocol for trauma victims can extend the role of ultrasonography.
- In patients with acute dyspnea, it can be very helpful to rule out the pathology.
- In pregnancy, for any airway or lung related problem ultrasound is very attractive option as it does not involve any ionizing radiation.
- Three dimensional ultrasound has increased the quality of imaging.
- Pocket based ultrasound is evolving which increase the availability of ultrasound imaging.
- Even pocket size smart phone based system for ultrasound with good quality is acceptable.
- Ultrasound for diagnosing basic pathology has a rapid learning curve and is beneficial to train suitable size workforce. The simplicity of ultrasound and its widespread use by inexperienced operators was evaluated in a study where an expert in ultrasound supervised the inexperienced to diagnose and exclude apnea and pneumothorax. There is a need for additional training to maintain basic ultrasound knowledge. Objective Structured Assessment of Ultrasound Skills (OSAUS) scale can be used to assess ultrasound competence in a reliable and valid way. The scores are helpful to determine if trainees are qualified for independent practice. Ultrasound is operator dependent and reproducibility is an essential part of qualification. Because of availability of portable ultrasound the skill of

ultrasound in airway management should be learnt by all clinicians for early diagnosis and treatment. Ultrasound will evolve as an integral part of airway management and future guidelines and teaching curriculum needs to be established for proper training. Guidelines are required to define training, competency and the scope of practice in airway management of ultrasound. Important topics to be covered include equipment selection and their function, basic physics of ultrasound, sonoanatomy, imaging skills related to clinical practice, image interpretation, ultrasound artifacts and safety issues.

Progression of intubation and ultrasound over the period-

In 1858, French paediatrician **Eugène Bouchut** developed the technique for non-surgical orotracheal intubation to bypass laryngeal obstruction resulting from diphtheria[78].

In 1880, Scottish surgeon **William Macewen** reported his use of orotracheal intubation as an alternative to tracheotomy in the setting of general anaesthesia with chloroform[79].

In 1913, **Chevalier Jackson** was the first to report a high rate of success for the use of direct laryngoscopy as a means to intubate the trachea[80].

Another pioneer in this field was **Sir Ivan Whiteside Magill** who developed the technique of awake blind nasotracheal intubation, Magill forceps, the Magill laryngoscope blade and several apparatus for the administration of volatile anaesthetic agents [81,82].

Sir Robert Reynolds Macintosh introduced a curved laryngoscope blade in 1943 which remains to this day the most widely used laryngoscope blade for orotracheal intubation[83]. Several manufacturers have developed video laryngoscopes which employ digital technology to generate a view of the glottis so that the trachea may be intubated[84,85].

Sir Ivan Magill introduced red rubber tubes of uniform internal diameter (ID) in 1930, and these remained the standard until **Mr David Sheridan** introduced plastic endotracheal tubes in 1959[86]. The recommendation for the use of uncuffed endotracheal tubes in patients younger than 8 years follows from the developing airway anatomy[86]. The shortcomings of uncuffed endotracheal tubes have been accepted and endured for 50 years.

Now cuffed paediatric tubes and microcuff tubes are also being used[28].

HISTORY OF ULTRASONOGRAPHY-

Lazzaro Spallanzani (1794) was the first to provide experimental evidence that non audible sound exist around us and made hypothesis that bats navigate in the dark using sound waves[87].

In 1880, the landmark discovery in the field of ultrasound by **Pierre Curie and Jacques Curie** was shown who discovered the piezoelectric effect, the basic scientific principal behind ultrasonography[88,89].

In 1915, **Paul Langevin** invented the first transducer hydrophone which was used during the First World War to detect submarine and icebergs[88].

The first physician to use ultrasound was **Karl Dussik** (neurologist and psychiatrist)[87,88]. In 1942 he used ultrasound to diagnose brain tumours. But as the brain is entirely surrounded by bone many of his ventriculograms were later shown to be mere artefacts[88].

In 1950, **Douglass Howry and Joseph Homes** pioneered 2D B-mode of ultrasound [90].

In 1958, **Ian Donald** pioneered the ultrasound in the field of obstetrics and gynaecology[89].

Moving pictures became possible with real time process in 1965 by **Krause and Soldner**[88]. In 1985, duplex sonography made flow imaging possible[90].

In 1989, **Daniel Lichtenstein** pioneered point of care of lung ultrasound in ICU[91]. Since 1995, 3D ultrasonography has opened new frontiers in the medical field[88].

ULTRASOUND IN ANAESTHESIA-

The first use of ultrasound in anaesthesia was in 1978, by **La Grange** where supraclavicular blockade of brachial plexus was facilitated with ultrasound[88]. This was the first study in which indirect sonographic approach was used for regional anaesthesia.

In 1994, **Kapral** published the first report on direct sonographic visualization in regional anaesthesia[92].

Ultrasound role is increasing in anaesthesia for obtaining vascular access, central venous cannulation, arterial cannulation, in regional anaesthesia for nerve blocks and transesophageal echocardiography tool for cardiac imaging[93]. Presently there is increasing role of ultrasound in airway screening and management.

ULTRASONOGRAPHY FOR ENDOTRACHEAL INTUBATION

Ultrasonography has wide applications regarding endotracheal intubation. First application is for the assessment of position of the ETT and second, for calculation of "correct" size of ETT.

One of the earliest report of using USG regarding intubation is published by **Slovis and Poland** in 1986 who were innovative to use USG for placement of ETT tip in 16 neonates[94].

Raphael et al in 1987 reported the use of USG for ETT placement for 24 intubated patients replacing the need for radiographs for the same purpose[95].

Chun et al (2004) used hand held USG for assessing ETT placement[71].

Ultrasonography is being evaluated for endotracheal tube placement for varied age groups, situations and diseases.

ULTRASONOGRAPHY FOR SUBGLOTTIC DIAMETER ESTIMATION AND SIZE OF ETT-

First report of use of USG for subglottic diameter estimation came from Montreal Children's Hospital, Quebec **in 2000** by **Giguère et al** in rabbit model to evaluate ultrasound (US) and a new videobronchoscopic (VB) technique [96].

The same group went ahead to translate their animal research to evaluate subglottic diameter in children in double-blinded, prospective clinical study in **2002**. **Husain et al** in this study used USG and videobronchoscopy for estimation of subglottic diameter to conclude that the USG measurement were smaller than videobronchoscopy[97]. But USG has gone far ahead to measure the same due to ease and availability.

Chidananda Swamy MN et al (2004) reviewed the applied aspects of anatomy and physiology of paediatric airway and suggested to have a good knowledge of difference between an adult and a paediatric patient for conduct of safe anaesthesia[19].

Lau et al in 2006 in their study came up with new formula for predicting length of ETT.

Lakhal et al (2007) have concluded that ultrasonography is a reliable tool to assess the diameter of the subglottic upper airway[98]. They compared the transverse diameter of the cricoid lumen assessed using USG and MRI in 19 healthy volunteers to find strong correlation between the two techniques with bias of 0.14 mm, a precision of 0.33 mm, and limits of agreement of -0.68 mm/0.96 mm

Marciniak (2009) suggested characteristic real-time ultrasonographic findings of the normal paediatric airway during tracheal intubation and its suitability for clinical use. It suggests that ultrasonography maybe useful for airway management in children, mainly for assessment of the position of the ETT.

Sibasaki 2010 concluded that that measuring subglottic airway diameter with ultrasonography facilitates the selection of appropriately sized ETTs in paediatric patients[66]. According to his study, ultrasound better predicted optimal outer ETT diameter than standard age- and height-based formulas.

Kajekar 2010 found that ultrasound is very useful in perioperative and intensive care management[99]. There is growing evidence of usefulness of ultrasound in assessment and management of potentially difficult airway. With proper understanding of sonoanatomy, there is increasing clinical application of ultrasonography in airway management in anaesthesia and intensive care.

Mandeep Singh (2010) has reviewed the sonographic details of the anatomic information of airway and has numerous potential clinical applications[65]. They could not visualize epiglottis in 29% (seven of 24) of volunteers in parasagittal plane because of acoustic shadowing by hyoid bone.

Kundra et (2011) all has described that ultrasound (US) imaging technique has recently emerged as a novel, simple, portable, non-invasive tool helpful for airway assessment and management[14].

Prasad et al in 2011 compared USG with CT as imaging tools for assessment of airway structures. They found that sonography could visualize all of the structures as reliable as computed tomography[100].

Bae et al (2011) findings show that ultrasonography offers a better alternative than the frequently used age-based tube selection method. However, even ultrasound is not always a reliable method in terms of choosing the correct tracheal tube size in children[10].

Chou in 2011 concluded that tracheal rapid airway examination by ultrasound for endotracheal tube placement for emergency intubation is feasible as it can be performed rapidly and considered as secondary confirmation method of endotracheal tube placement[101].

Arun Prasad (2011) showed that USG can reliably image all of the structures visualized by CT, and in general, infrahyoid parameters agree well between the two modalities, as opposed to suprahyoid parameters, which may be affected by unintentional head extension[100].

Adhikari in 2011conducted a pilot study to determine the utility of point-of-care ultrasound in the assessment of difficult laryngoscopy[102]. The sonographic measurements of anterior neck soft tissue were greater in the difficult laryngoscopy group compared to the easy laryngoscopy group at the level of the hyoid bone[102].

Schramm in 2012 measured minimal transverse diameter of subglottic airway by ultrasound facilitates selection of the appropriate ETT in paediatric patients and may reduce the number of re-intubations[15].

Kim E J et al (2013) validated the ETT size determination using US measures of SD before intubation to establish an empirical formula for ETT fitting based on SD and biographic parameters[13]. As per their observation, US-measured OD-ETT at SD was in good agreement with the actual OD-ETT, suggesting that US-measured SD helps in choosing the appropriate ETT diameter for children. In children older than 12 months, the equation 'OD (mm) $=0.01 \times$ age (months) $+ 0.02 \times$ height (cm) $+ 3.3$' may help select the appropriate ETT.

Or et al (2013) studied multiplanar 3D ultrasound images and compared visually with corresponding MRI and cadaver anatomical sections to assess the anatomy of the upper airway and measure the subglottic and tracheal diameters in adults[103]. They found strong correlation for the AP diameter measurement and moderate correlation for the transverse diameter measurement of the subglottic space, and a strong correlation for the transverse diameter measurement of the upper trachea, in the ultrasound and MR images[103].

Parmar et al (2014) evaluated the feasibility of bedside sonography as a tool for airway assessment to describe sonographic anatomy of airway in 100 adult volunteers. They found USG as a safe method to assess the airway which can provide real-time dynamic images relevant for several aspects of airway management.

Hiruma et al in 2015 reported a case of detection of bronchial intubation using lung ultrasound in an infant which was not previously identified by auscultation[104].

Patients and methods-

a) **IRB approval –**

This study was approved by institutional review board of Christian Medical College, Vellore with IRB Min no : 8846 date 7/4/2014

b) **Type of study-**

The study was designed as prospective observational study.

c) **Settings**:

The study was carried out at the Paediatric surgery operating room under Paediatric Anesthesiology unit of Department of Anesthesiology, Christian Medical College, Vellore, Tamil Nadu, India.

d) **Study period** –

April 2014 till August 2015.

e) Participants:

Inclusion Criteria:

i. Children with age less than six years
ii. Children posted for elective surgery
iii. Children undergoing general anaesthesia with endotracheal intubation

Exclusion Criteria:

i. Difficult airway

ii. ASA grade 3 and 4

iii. Children posted for emergency surgery

iv. General anaesthesia with measures other than ET tube such as laryngeal mask airway

v. Parents refusing to give informed consent.

f. Informed written consent –

Consent, obtained from parents in children less than six years old scheduled for elective surgery planned with general anaesthesia using endotracheal intubation, was taken by investigators in the evening prior to surgery day.

g. Sample size calculation-

The required sample size to show that the proportion of intubated correctly by the age based formula as compared to the ultrasound was found to be **63 children** with 90% power and 5% level of significance with a difference of about 29%(difference between the two methods). **(Bae et al)[10].**

Proportion of successful intubation using Age based formula- 31/100

Proportion of successful intubation using ultrasound- 60/100.

Following formula for single mean- paired t test has been used

$$n = \frac{\left(z_{1-\alpha/2} + z_{1-\beta}\right)^2 \text{ x2x PQ}}{d^2}$$

$$P = \frac{31\% + 60\%}{2}$$

Q=100-P

d= difference (29%)

f. Age based formula for ETT internal diameter

The most commonly used formula for selection of ETT for children more than two years of age is Cole’s formula. (age in years)

Internal diameter of tube in mm = $\frac{Age}{4} + 4$

g. Calculation of length of the tube

For children more than 2 years of age, following formula was used to measure the Length of tube.

Length of tube = 12 + Age in years /2

For the children less than 2 years of age, following chart was used for calculation of diameter and length of ETT.

Age	**ID (mm)**	**Length OT (cm)**
Newborn	3	9
3months	3	10
3-9months	3.5	11
9-18 months	4.0	12
1.5 – 2 years	4.5	12

Table 1 – Chart for the measurement of diameter and length of the ETT using age.

The size of the age based ETT (internal diameter) and length of the tube was calculated in the previous evening while taking consent and was noted down in the patient proforma, to be compared at the time of induction.

f**. Ultrasound measurement-**

All the measurements have been carried out by the professor of the anesthesia trained in the paediatric anesthesia and experienced for use of ultrasound in anesthesia. The investigator was trained by a radiologist for two weeks for measuring cricoid dimension and related anatomy. The measurement was taken at transverse diameter of cricoid cartilage at air mucosa interface. Three readings were taken for each patient and a mean was calculated to select USG ETT. All the images were saved in flashcard of ultrasound machine and analyzed by radiologist later on.

Standardization of induction of anesthesia and ultrasound assessment-

A pilot analysis had been carried out to measure the subglottic diameter in the operation theatre over 15 patients following the same technique with the radiologist present and supervising during scanning.

USG measurement of transverse subglottic diameter at cricoid level was performed using portable ultrasound machine (Venue 40, GE healthcare systems). The hockey stick probe of frequency 7-15 Hz was used. B mode of ultrasound was used.

Figure 8 - GE ultrasound machine venue 40

Figure 9 - Hockey stick probe with frequency of 7 – 14 Hz

As per institutional protocol, anaesthesia was induced through facemask with 3 litres oxygen and 3 litres nitrous oxide with Sevoflurane (4-8%) as inhalation agent. Standard monitors were attached (electrocardiogram, non-invasive blood pressure, pulseoximeter, capnometer) and intravenous line was secured. Injection fentanyl 1 microgram per kg was given followed by Injection Propofol 1 -2 mg per kg body weight. Patient was mask ventilated with oxygen 6 litres per minute. Patient was paralysed with muscle relaxant Atracurium 0.5 mg per kg body weight (after loss of consciousness). Mask ventilation was carried out for three minutes. USG imaging done to determine subglottic diameter after stopping mask ventilation so as to acquire clear image (ventilation is interrupted only for less than 20 seconds).

With head in neutral position with slight extension, the linear probe was placed on the middle of anterior region of neck. Hyoid bone was visualized, appearing as an inverted ‘U’ shaped hyper-echoic curvilinear line. On caudal movement of the probe, vocal cords appear as two hyper echoic structures forming an isosceles triangle. On further moving the probe caudally, cricoid arch was seen.

Subglottic diameter was defined as the diameter at the transverse air column at cricoid cartilage level, measured between the margins of cricoid cartilage at highest possible resolution at air mucosa interface. Three readings of subglottic diameter were measured for each patient and final reading was calculated by taking a mean of all three readings. The images scanned during the study were saved.

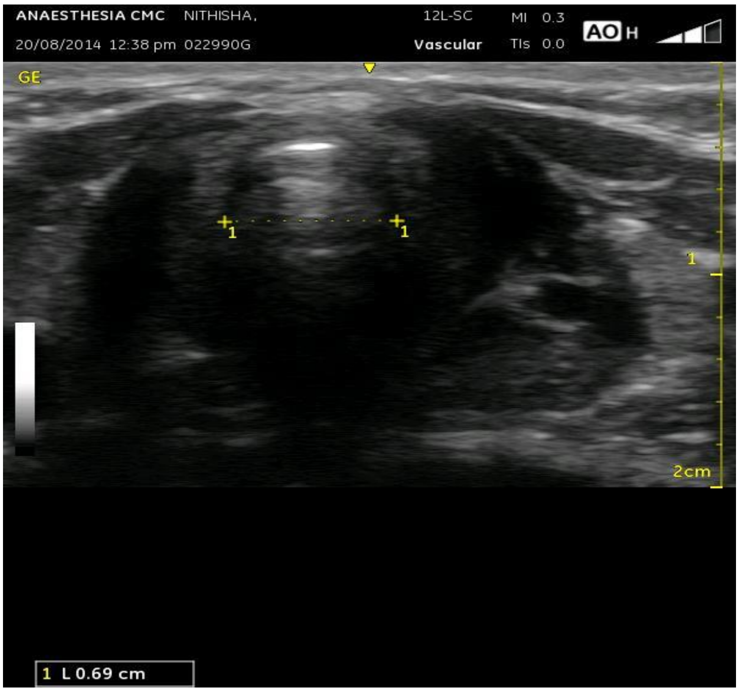

Figure 10 – USG midline transverse image of cricoid

g. Decision of USG tube size and subglottic diameter –

Depending upon ultrasound measurement of subglottic diameter, USG ETT was chosen (Table 2). The outer diameter of ETT was smaller than measured subglottic diameter and was never exceeded. After intubation with correct tracheal tube, length of tracheal tube was decided by black mark at vocal cord and length of ETT at incisors noted (checked with auscultation of bilaterally equal air entry)

ETT size (internal diameter)	Outer diameter of tube
2.5	**3.5mm**
3	**4.2mm**
3.5	**4.8mm**
4	**5.5mm**
4.5	**6.2mm**
5	**6.9mm**
5.5	**7.6mm**

Table 2 - Internal and external diameter of the ETT followed with subglottic diameter values.

h. **Primary Outcome** –

The tube size was calculated using both the methods (age based formula and ultrasound method). The correct tube used for the patient was confirmed by air leak test, carried out after intubation at 10-20 cm of H_20. Tube size considered optimal if tracheal leak was detected at inflation pressure of 15 to 20 cm H_2O on the ventilator with un-cuffed tube of Portex Tracheal Tube Company. If there was no leak at 30cm of H_2O, 0.5mm size smaller tube was selected. If leak occurred at inflation pressure less than10 cm H_2O, 0.5 mm larger tube size selected. Uncuffed tube of same manufacturer was used as outer diameter is different in same size tube of different manufacturers.

h. Statistical methods:

Mean and standard deviations were calculated for the agreement for correct ETT used with each of ultrasound ETT and age based formula. ETT was assessed using Intra class correlation (ICC). Kappa value had been calculated to show the agreement of correctly and incorrectly identified measurements across ultrasound and age based formula. Proportion of correct ETT used with the age based formula and with that of ultrasound is compared using MacNemar's test. Length of tube by age based formula and direct visualisation at vocal cords has been analysed by using paired t test.

Subgroup analysis-

The similar analysis was carried in the subgroups in terms of

a. age less than one year of age Vs more than one year of the age,
b. boys versus girls
c. weight of less than five kg, five to twenty kg, more than twenty kg

The correct selection rates of the two methods, namely the age based formula and ultrasound method were compared using McNemar's test. Data entry was done in Microsoft excel sheet 2010 and the data was analysed using SPSS Version 17.

Results –

Total sixty six children with mean age of 27.9 months (SD 19.6 range- one week to 72 months) were recruited for this prospective observational study after the informed written consent from the parents.

Demographic distribution-

a. **Sex Distribution-**

Out of 66 children recruited, 47 (71%) were boys and 19 (29%) were girls. (Figure 11)

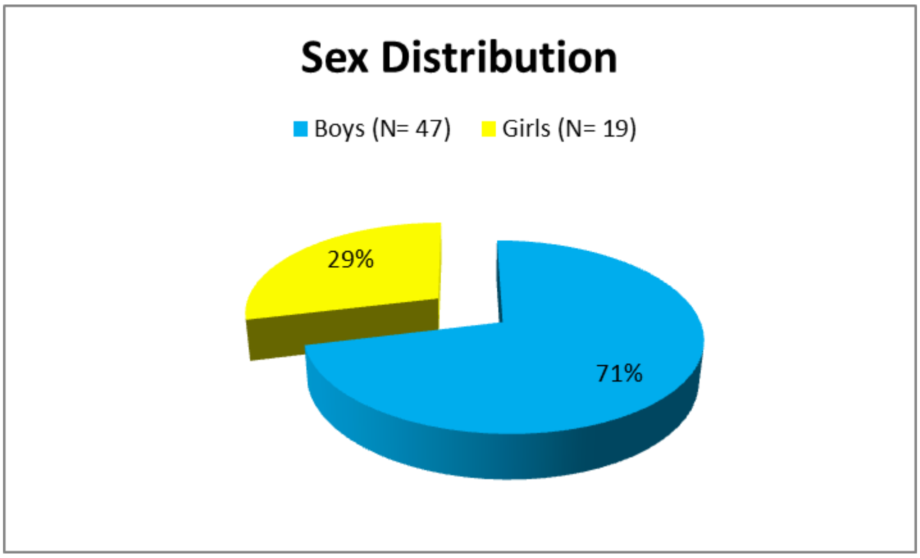

Figure 11– Depicting the percentage of boys and girls recruited for the study

b. Age Distribution-

21 children were less than or equal to one year of age at the time of procedure. 45 children were more than one year and less than six years of age. (Figure 12)

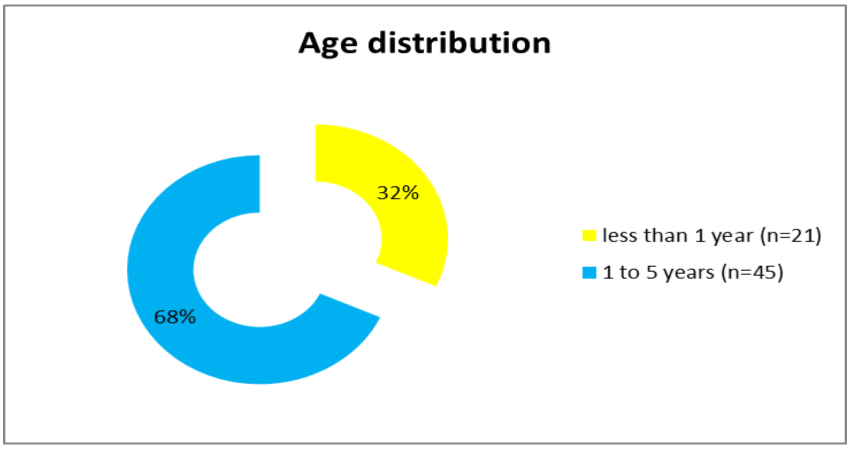

Figure12 - Age distribution with 32% of the children less than one year.

c. Weight Distribution –

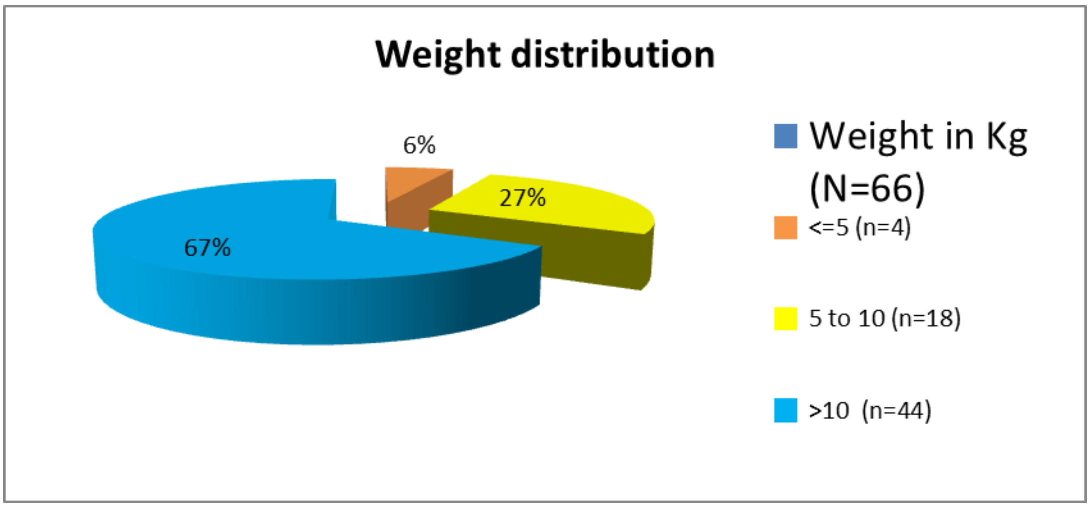

Figure 13 – Pie chart showing 3 groups of children in terms of weight.

Mean weight of the 66 children recruited, was 11.5 kg (SD 3.9, range 3.88 to 23.9 kg). Four (6%) and eighteen (27%) out of sixty six children had body weight less than five kg and between five to ten Kg respectively. Forty four children had weight of more than 10 kg. (Fig 13)

d. Height distribution –

Average of the height of the 66 children was 85.6 cm (SD 17.1, range 48 to 112 cm).

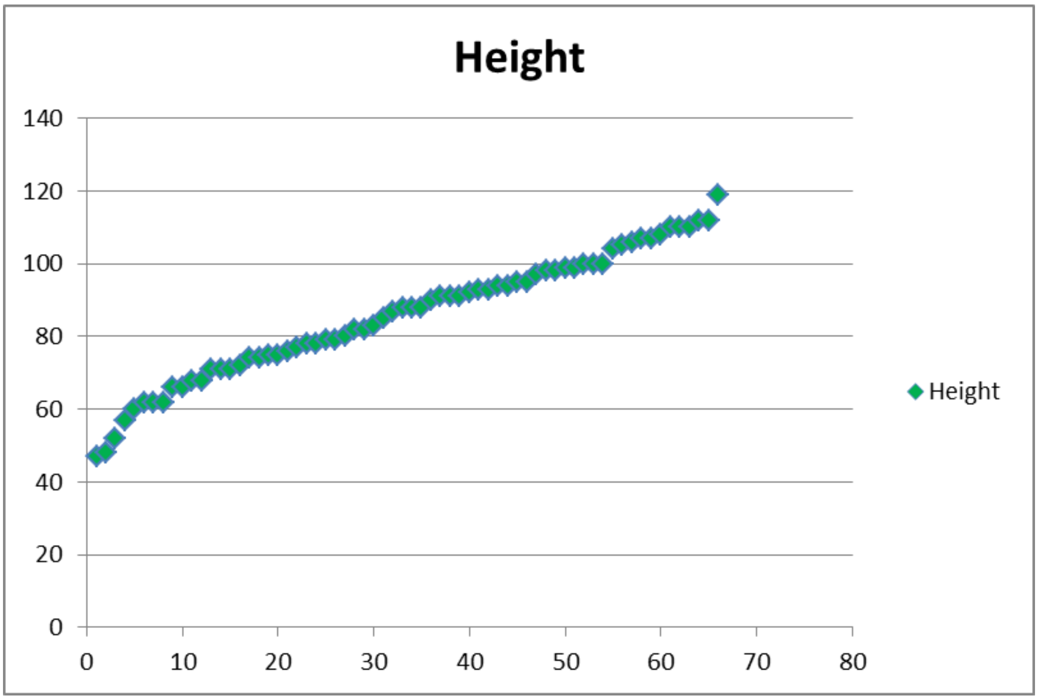

Figure 14 – Graph showing the height distribution of 66 children in ascending order.

ASA Grade-

As per the inclusion criteria, only ASA grade I and II patients were included for this study. 53 (80%) children were classified as ASA grade I while 13 children were ASA grade II (20%).

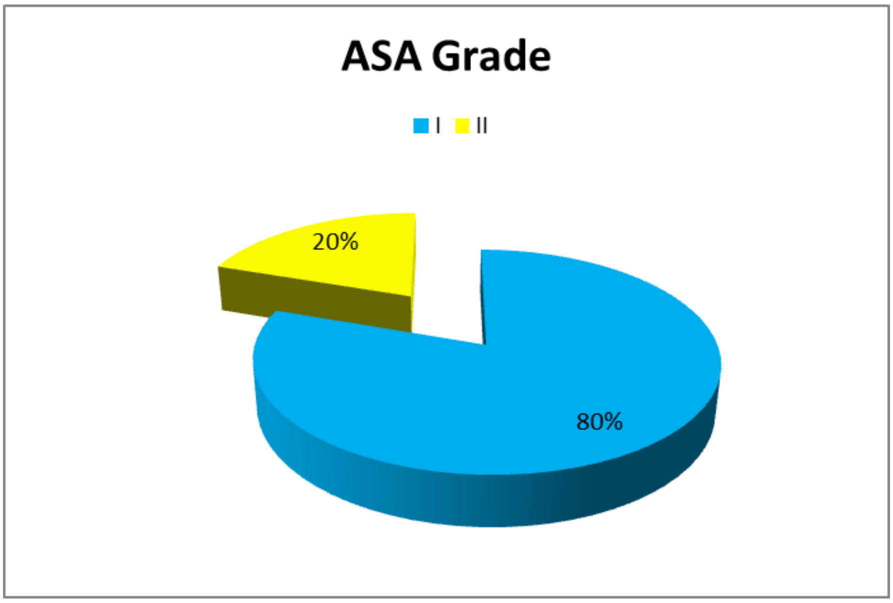

Figure 15- Pie chart with classification of recruited patients according to ASA grade.

Size of ETT by age based formula –

Mean of size of ETT diameter, calculated using age based formula (Cole's formula) was 4.3 mm (SD 0.6, range 3 to 5.5 mm).

Subglottic diameter and diameter of ETT calculated by USG-

Mean subglottic diameter as measured using ultrasound was 6.1 mm (SD 0.9, range 4.6 to 8.8). As pert the recommendations (ref) the USG tube size was calculated following the subglottic diameter. Mean of size of these ETT was 4.6 mm (SD 0.6, range 3.5 to 6).

Correct size ETT which was actually used-

Mean of the correct size ETT was 4.7 (SD 0.6, range 3.5 -5.5). This value is more than the means of both ETT calculation using USG method and age related formula.

Diameter (mm)	Mean	SD	Range	
			Minimum	Maximum
Subglottic diameter	6.1	0.9	4.6	8.8
ETT by age based formula	4.3	0.6	3	5.5
ETT by USG	4.6	0.6	3.5	6
Correct ETT	4.7	0.6	3.5	5.5

Table 2 – Details of the subglottic diameter and ETT using age based formula, USG methods and correct ETT tube.

Agreement between two methods of tube size calculation and correct ETT –

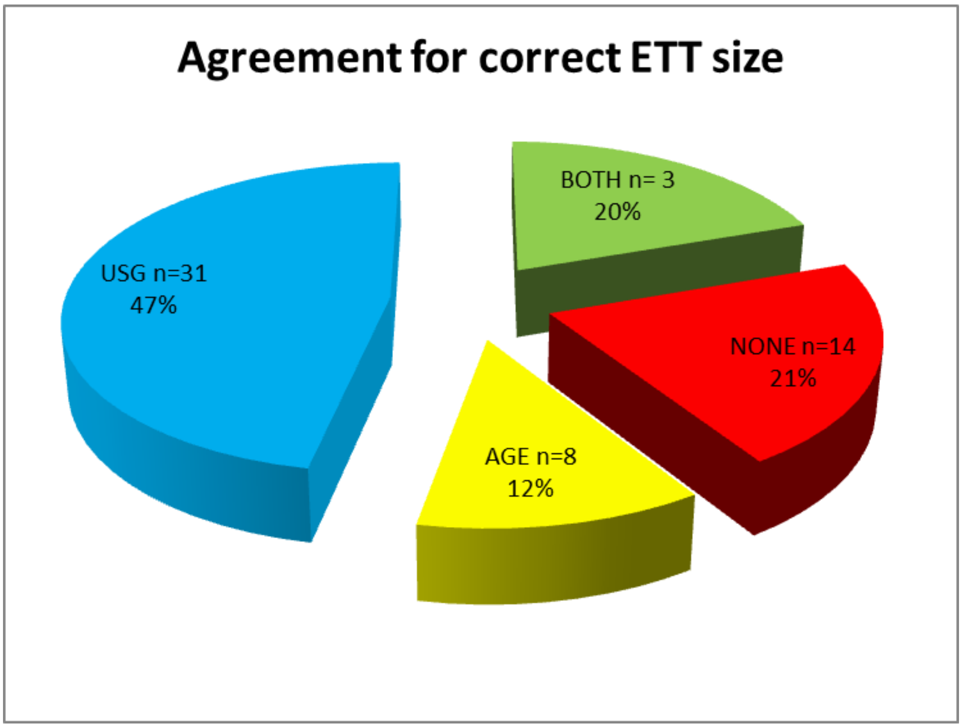

Figure 16 - Pie diagram for the agreement between calculated ETT and correct ETT size shows that the ultrasound provided better prediction of ETT size in children (67% of children). Age based formula was correct in 32 % of the cases.

N =66	USG based ET tube match with correct tube size			
Age based formula ET tube match with correct tube size		**Yes**	**No**	**Total**
	Yes	13 (20%)	8 (12%)	21 (32%)
	No	31 (47%)	14 (21%)	45 (68%)
	Total	44 (67%)	22 (33%)	66

Table 3 – Match between correct ETT used versus ETT calculated by USG and ETT calculated by age based formula tube formula ET tube with correct ETT size.

Size of correct ETT matched with ETT size calculated using USG method is 44 patients (67%), whereas the age-based method selected the correct tracheal tube size in 32% (21) patients. This difference was statistically **significant (p <0.001 using McNemars test)** proving the superiority of ultrasound method over age based method. Comparisons of means of sizes of correct ETT with age based formula and with USG guided size was carried out separately using paired t test which had the statistically significant association.

	Paired difference				
	Difference of means	**SD**	**Std. error Means**	**95% confidence limit**	
Pair 1 – Age based ETT & ETT size used	-0.40	0.32	0.04	-0.48 to -0.32	0.00
Pair 2 – USG based ETT & ETT size used	-0.15	0.34	0.04	-0.24 to -0.075	0.00

Table 4 - Paired t test carried out to know the significance of the paired values of both the methods (USG based and age based method with the correct size ETT)

Reliability Agreement of age based formula and correct tube size-

Intraclass correlation coefficient (ICC) was calculated to know the reliability agreement for the size of ETT which was used for the patient with the size of ETT calculated using age based formula. Agreement of ultrasound based method with the correct size tube was 0.902 is considered as excellent also supported by good 95% confidence limit. However the same ICC for agreement for age based formula method and correct ETT was also 0.835 which is considered good. These values suggest that USG based methods is better than age based formula in children.

	ICC	**95% confidence limit**
Agreement of USG and correct ETT size	**0.902**	0.807-0.946
Agreement of age based formula and correct ETT size	**0.835**	0.012-0.946

Table 5 – Intraclass correlation coefficient values with 95% confidence limit for agreement of correct ETT size and both methods.

Subgroup analysis –

a. Boys vs. girls –

N=66	Mean correct tube size	Mean age base tube size	Mean USG base tube size
Male (n=47)	4.77	4.31	4.7
Female (n=19)	4.82	4.53	4.42

Table 6 - Mean age based and USG based correct tube size.

The mean USG based tube size was similar to the mean correct tube size in males (4.7). However it was less in females (4.42). Mean age base tube size was found to be different from the mean correct tube size in both males and females.

N=66	Agreement between age based and correct tube size	Agreement between USG and correct tube size
Male (n=47)	0.822	0.968
Female (n=19)	0.879	0.65

Table 7 - Agreement between age based and USG based ET tube with correct tube size with ICC.

Agreement between USG based tube size and correct tube size was greater than age based tube size in boys. (Table 7). However agreement between USG based tube size and correct tube size was less in females (0.65).

b. Body weight and calculation of correct size ETT-

Weight (N=66)	Mean of correct ETT size	ETT with age based formula	ETT with USG method
<=5 kg (n=4)	3.63	3	3.62
5 - 10 kg (n=18)	4.19	3.81	4.08
>10 kg (n=44)	5.12	4.72	4.93

Table 8 - Mean age based and USG based tube size, according to weight of children

Weight (N=66)	Agreement for correct ETT vs. age based method	Agreement for correct ETT size vs. USG method
<=5 kg (n=4)	0	1
5 - 10 kg (n=18)	0.602	0.828
>10 kg (n=44)	0.521	0.685

Table 9 - ICC value suggesting the agreement for correct ETT size and both the methods.

The mean USG based tube size was similar to the mean correct tube size in children weighing less than or equal to five kg (3.6). The mean for the age based tube was less in this category (3). In children weighing 5-10 kg or more than 10 kg, the mean of USG tube and age based tube was less than mean of correct tube. However, the mean of USG based tube size was closer to the mean correct tube size.

Agreement between USG based tube size and age based tube size with correct tube size, stratified by weight was also analysed. The agreement between age based tube size and correct tube size was nil in children less than or equal to five kg weight whereas, there was perfect agreement (1) among the USG based tube size and correct tube size in this category. In children having weight ranging from 5-10 kg or more than 10 kg, the USG based tube size showed a better agreement with correct tube size than the age based one.

c. Age and correct ETT size-

Weight (N=66)	Mean of correct ETT size	ETT with age based formula	ETT with USG method
<= 1 year (n=21)	4.09	3.6	4
> 1year (n=45)	5.1	4.7	4.9

Table 10 – Means of the sizes of correct ETT, ETT with age based formula USG method in children less than one year and more than one year of age.

Mean of correct ETT used was more than that of age based method and ultrasound method in both the age groups. However the ETT diameter of used tube matches very closely with USG based method in both age groups, more closely in children less than one year (4.09 vs. 4 mm)

AGE (N=66)	Agreement for correct ETT size vs. age based method	Agreement for correct ETT vs. USG method
<= 1 year (n=21)	0.717	0.948
> 1year (n=45)	##	0.408

Table 11 – Agreement with ICC values between correct tube used and USG based method

ICC value for agreement shows excellent correlation between correct ETT size and USG method especially in children with one year or less. Age based method did not match with correct ETT as good as USG based method. Especially in children more than one year of age, agreement for correct ETT size versus age based method could not be calculated with software, whereas agreement for correct ETT and USG method is 0.408.

Correct length of ETT and length calculated with age based formula –

			Range	
Length (cm)	**Mean**	**SD**	**Minimum**	**Maximum**
Length of tube using age based formula	12.6	1.4	9	14.5
Length of correct ETT size (by confirming black line at vocal cords)	12.3	1.6	9	14

Table 12 - Mean and range of the length of the ETT which was used actually and ones calculated using age based formula.

Mean of length of tube using age based formula is 12.6 (SD of 1.4, range 9 to 14.5) which is close to the mean of length of actual ETT used that is 12.3 (SD of 1.6). **(p= 0.001).**

Values in both the groups matched in 28 patients while 36 patients the values strong correlation of 0.910 (95% confidence limit of 0.83 to 0.94) was observed between these two groups.

There is stronger correlation between <1year children (0.848) than >1year old (0.545). This suggests that any of the two methods can be used for selection of correct length of tube.

Age group	**N**	**ETT length**	**Mean**	**ICC**
<= 1 year	39	Length with age based formula	11.7	0.848
		Correct length of ETT used	11.4	
> 1 year	27	Length with age based formula	14	0.541
		Correct length of ETT used	13.5	

Table 13 – Number, mean and ICC values for the length of ETT used, length with age based formula.

DISCUSSION

Most remarkable achievement in the anaesthesia over last century is the safety which has made the utmost of the surgical interventions possible[105]. Endotracheal intubation is one of the factors which has made the safe induction of anaesthesia possible[105].

Review by Kristensen et al (2014) highlights the new beginning in the anaesthesia with ultrasonography playing active role for clinical decision-making and intervention in airway management[11]. Numerous studies are being published for adult and paediatric population using the ultrasound method for airway management[10,11,13,14].

The age based formula of age/4 + 4 has been assessed in children for the correct ETT size estimation and compared with the ultrasound method by Bae et al[10]. Their sample size was 100 with mean age of 39 months, mean weight of 14.6 kg, and mean height of 95 cm. These values of age, weight and height were 27.9 months, 11.5 kg, 85.6 cm respectively in our study population which are significantly less than Bae et al's population (p=0.005, 0.005, 0.002 respectively for age, weight and height). This fact signifies that the population we have in our study is younger and smaller children as compared to population studies by Bae et al[10].

Our observation of 67% (47% USG method +20% both) of correct estimation of ETT size is higher than estimated by Bae et al study. Age based method in their study was correct for 31% patients whereas the same formula calculated correct ETT size in 32% of the children in our population.

Shibasaki et al (2010) have separately analysed the agreement between the cuffed and non-cuffed ETT tubes to have an agreement of 98% and 96% respectively[12]. Our finding of 0.902 kappa value for agreement of USG and correct ETT suggests the similar observation. In our study, cuffed tubes were not used in the recruited age group as per the institutional practice.

Gupta et al also have carried out the study to predict the ETT size using USG and age based formula method[16]. Age group which was recruited in this study ranged from 3 to 18 years which very obviously differs from age of our population which ranges from 1 week to 6 years. Another striking difference with their study is the use of "cuffed tube" contrasting with uncuffed tube in our study which makes it unfair to compare both. Moreover, the correct number of patients in whom the USG method estimated the correct tube in not very clear from their results and data.

Schramm et al (2012) have conducted the study to assess the ETT size using ultrasound which was claimed to be to the first from Europe[26]. Though, they have concluded that ultrasound was better than age based formula to get correct ETT, only 48% of the patients had correct size provided by USG method in the 50 children similar age group as our study.

Another observation which makes the study by Schramm et al thought-provoking is about the effect of learning effect which they think need not be included in the analysis[26]. Lakhal et al have reported that the subglottic diameter can be measured using the ultrasound up to the precision of 0.33mm[98]. In our study, all the ultrasound examination was carried out by senior anaesthetist trained in paediatric anaesthesia and ultrasound. Despite of that, the pilot analysis was conducted before actual recruitment for this prospective study which allowed us to standardise the ultrasound procedure under the supervision of radiologist[98] .We recommend training in ultrasound scanning for all ultrasound related studies done by anaesthetists as there is a steep learning curve .

Subgroup analysis carried out in our study hints towards some interesting findings. Reliability agreement for boys verses girls was found to be 0.9 for boys (n=45) while the same was 0.6 for the girls (n=19). Possible explanation for this difference may be the anatomic difference between the boys and girls larynx. Another observation which needs to be taken forward is about complete agreement between the correct ETT and USG method in children of body weight less than 5 kg. Even though the number was too low to definitively comment, this observation can be the key step in the induction of the anaesthesia for new born and infants.

Ideal situation would have been the randomised controlled trial for the use of correct size ETT calculated using USG based method and age based formula method. But due ethical issues related to the standard of care, randomisation is not possible while calculating the correct ETT size. This fact has forced us to conduct the nonrandomised prospective observational study which gives rise to level II evidence.

For length of ETT Lau et al suggested that the routinely used age based formula is underestimating the length of ETT and came with new formula age /2 + 13 for > 1 year and weight /2 +8 for < 1 year old[106].

In our study we found age based formula and depth marker method have strong correlation with each other and both can be used to guide proper length of ETT.

Eck formula for endotracheal tube considering age, height and weight is[44]:

Internal diameter of ETT = 2.44+ (age x 0.1) + (height in cm x 0.02) + (weight in kg x 0.016).

Sibasaki et al analysed their correlation using the formula using subglottic diameter and age and height separately for calculating the outer diameter of ETT. ETT OD measured with **0.027 x (age) +5.2** had

R^2 of 0.76 for cuffed, and **0.030 x (age) + 5.4** had R^2 of 0.76 for uncuffed ETT[66]. Correlation of optimal ETT size calculated using height was also carried out in their analysis**. 0.037 x (height) + 2.9** had R^2 = 0.79 for cuffed and an OD of **0.044 x (height) + 2.6** had R^2 = 0.82 for uncuffed tubes[66].

Kim came with formula n children older than 12 months, the equation **OD (mm) = 0.01 × age (months) + 0.02 × height (cm) + 3.3** which may help select the appropriate ETT.

Proposed formulas-

Compiling the findings from our analysis using anova test and linear correlation, we proposed the formula for predictions of correct size ETT.

There is a good correlation between outer diameter of endotracheal tube and subglottic diameter.

Outer diameter of ETT =1.76 + 0.78 (subglottic diameter on USG) with R^2= 0.699

Considering age (months), weight (kg) and height (cm) as variables

Outer diameter of ETT = 3.66 + (0.004 x age) + (0.06 x weight) + (0.025 x height)

With this formula, there was correlation (R^2) was 0.716

With age as the only variable, proposed formula,

Outer diameter of ETT = 5.66 + (0.034 x age) had R^2 = 0.611

With height as the only variable, proposed formula is

Outer diameter of ETT = 2.94 + (0.043 x height) had R^2 = 0.72

With weight as the only variable, proposed formula is

Outer diameter of ETT = 4.43 + (0.18 x weight) had R^2 = 0.688

Analysis of height and outer diameter of endotracheal tube with R^2 =0.72 shows that height is the most important variable as compared to age (R^2=0.611) and weight (R^2=0.688).

LIMITATIONS-

There are some limitations in this study such as

a) The leak test was assessed clinically and interobserver or intraobserver variability in leak test has not been ruled out. There is no practical test other than leak test to determine correct ETT size.

b) USG can't view posterior wall of trachea due to acoustic shadow. It can't provide information on antero-posterior diameter.

c) Randomised controlled study would have been the ideal one instead of the observational to provide the level1 evidence. But randomisation in this type of intervention is not possible due to ethical issues.

d) There is also a need to include using cuffed / micro cuffed tube which will decrease the number of re-intubation of age based formula.

CONCLUSION

In our study ultrasound predicted the correct tube size in 67% of the population while age based formula predicted correct tube size in only 32%.Therefore we conclude that ultrasonography is a better tool for selecting paediatric ETT size as compared to age based formulas.

USG has a definite advantage over age based formulas in children less than one year of age and less than five kg of body weight for calculations of ETT size.

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ANNEXURES-

CONSENT FORM

Study Title: A randomized control trial for selecting correct uncuffed endotracheal tube size in paediatric population

Participant's name: ………………………………………

Date of Birth / Age (in years):………………………………..

I____

___________, parent/ guardian of ___________________________________

(Please tick boxes)

Declare that I have read the information sheet provide to me regarding this study and have clarified any doubts that I had. [ ]

I also understand that my child's participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]

I also understand that neither I, nor doctors, will have any choice or knowledge of method of selection of endotracheal [ ]

I understand that I will receive free treatment for any study related injury or adverse event but I will not receive any other financial compensation [ ]

I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]

I understand that my identity will not be revealed in any information released to third parties or published [ ]

I voluntarily agree to take part in this study [ ]

Name:

Relation to participant:

Signature:

Date:

Name of witness:

Date:

PATIENT INFORMATION SHEET

Title- Randomised controlled trial comparing ultrasound method with age-related formulas for pediatric endotracheal intubation.

You are requested to participate in this study where we will randomly calculate the endotracheal tube size diameter either using a age based formula or ultrasound method.

Q: What will be done for this research trial?

A: Your child is being given anaesthesia through the injectable drugs and gases. The gases and the oxygen are continuously provided through a tube which will be put his respiration airway (trachea) through larynx (throat) after he is unconsious. This tube is called as Endotracheal tube (ET tube). It is very important to use the correct diameter tube to prevent it from moving and causing a gas leak. It is little difficult in children to decide the correct size of ET tube because of small size of the airway and larynx.

There are two methods available at present to calculate the desired size of ET tube. First method is the formulas based on patient's age and height. Second method is to measure the diameter of airway using ultrasound method and then use the corresponding tube size. Both methods have been established in children in previous studies.

This study aims to compare these both methods in same settings. In this research study, around 124 children will be recruited. Randomly, in half of the children the tube size will be calculated using age based formulas and other half children will receive ET tube by calculating the diameter using ultrasound. The need of revising the ET tube will be assessed to know which a better method is.

In this study, once you give the consent, we will randomly choose a method to calculate the ET tube size for your child.

Q: Will the participation cost me any money?

A: Agreeing to participate will not add any cost to your child's surgery and anaesthesia charges. The procedure of anaesthesia remains unchanged if you participate or do not participate.

Q: Will I be given any remuneration for participating in the study?

A: Participation in the study is voluntary and there is no remuneration or incentive for participation.

Q: What if I do not agree to participate in the study?

A: The anaesthesia procedure remains same even if you refuse. You will continue to get the usual care whether or not you participate in the study.

Q: What if I decide to change my mind after initially agreeing to participate?

A: This is a single time procedure without any change in anaesthesia or postoperative care of your child. Therefore the question of withdrawing the consent does not arise. But you can refuse of participate.

Q: How will I benefit from the study?

A: Your child may not get any direct benefits from this study but the knowledge received from this study will be of immense importance for the future generations.

Q: Is there any compensation for study related injury?

A: No, as there is no question of study related injury there is no compensation provided. Both the methods for calculation of ET tube are being used around the world. There can be a complication of the anaesthesia procedure but not related to the protocol followed in this study.

Q: Who will have access to the information in the study?
A: Only the investigators of this trial will have access to information related to the study. All the information will be kept confidential. The final outcome of this study will be published as postgraduate thesis and scientific publication in journals without revealing your or your child's identity.

Q: Who should I contact if I have additional questions?
A : You may contact Dr. Reena Pal for any further query.

Contact number – 9585639372

Email- drrreenasanjay@gmail.com

Address- Postgraduate registrar , Dept of of ansthesia, CMC Vellore 632004.

Utility of ultrasound for selecting correct uncuffed endotracheal tube size in paediatric population

Date: …………………………

Serial no: ……………..

Name : ……………………………………………………………….

Hospital no: ……………………………………………………..

Age: ……………..Months …………………Years

Sex: 1. Male ☐ Female ☐

Weight: ……………………….kg

Height: ………………………...cm

ASA grading: I ☐ I ☐

Surgery: ………………………………………………..

Endotracheal tube size by age based formula: …………………………………..

Subglottic diameter by ultrasound: ……………………………………………………

Endotracheal tube size by ultrasonography: ………………………………………

No. of endotracheal intubation attempts: ☐

Leak at 20 cm of water: …………………………………..

Complication: 1. Yes ☐. No If ☐……..……………………………………

Correct tube size: …………………………………..

Length of endotracheal tube by age based formula: ……………………………

Correct length of tube: ……………………………………………………

Comments:…………………………………………………………………………………………
……

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………

ஆய்வில் பங்கேற்பதற்கான தகவல் படிவம்

குழந்தையின் மூச்சுக்குழலுக்குள் செலுத்தப்படும் குழாயின் அளவை அளக்க, வயது தொடர்பான சூத்திர முறையையும், அல்ட்ராசவுண்ட் கருவி முறையையும் ஒப்பிடும் ஆராய்ச்சி.

உங்கள் குழந்தையை இந்த ஆராய்ச்சியில் பங்கேற்க அனுமதிக்குமாறு கேட்டுக்கொள்கிறோம்.

1. இந்த ஆய்வில் என்ன செய்யப்படும்?

உங்கள் குழந்தைக்கு அறுவை சிகிச்சையின்போது வலி தெரியாமல் இருப்பதற்காக மயக்க மருந்து கொடுக்கப்படும். பொதுவாக மயக்க மருந்து கொடுக்கப்படும்போது, குழந்தையின் மூச்சுக்குழாயினுள் ஒரு செயற்கை குழாயினை செலுத்தி, அதன் வழியாக மயக்க வாயு மற்றும் பிராணவாயு கொடுக்கப்படும்.

இந்த குழாயினை மூச்சுக்குழலுக்குள் செலுத்தும் குழாய் என்று பொருள். சரியான அளவை கொண்ட குழாயினை பயன்படுத்துதல் மிகவும் முக்கியமாகும். சரியான அளவுடைய குழாயினை பயன்படுத்துவதினால் குழாய் நகர்வதையும் மற்றும் வாயு கசிவையும் தடுக்கலாம். சரியான அளவையுடைய குழந்தையின் அளவோடு ஒத்துப்போகும்படியான அளவை கண்டுபிடிப்பது கடினம், ஏனென்றால் குழந்தைகளின் மூச்சுக்குழாய் மிகவும் சிறியதாக இருக்கும்.

இந்த ஆய்வில் சரியான அளவினை கொண்ட குழாயினை பயன்படுத்த இரண்டு முறைகள் பயன்படுத்தப் படுகின்றது. ஒன்று, குழந்தையின் வயதின் அடிப்படையில் கொண்டு அளவு கணக்கிடப்படுகிறது.

மற்றொன்று அல்ட்ராசவுண்ட் முறையின் மூலம் மூச்சுக்குழாயின் அளவை கணக்கிட்டு அதாழலம் கணக்கிடப்படுகின்றது.

ஆய்வில் பங்கேற்பவர்களுக்கான ஒப்புதல் படிவம்

தலைப்பு:

குழந்தையின் மூச்சுக் குழலுக்குள் செலுத்தப்படும் குழாயின் அளவை அளக்க வயது தொடர்பான சூத்திர முறை மற்றும் அல்ட்ராசவுண்ட் கருவி முறையையும் ஒப்பிடும் ஆராய்ச்சி

ஆய்வில் பங்கேற்பவரின் பெயர்:

பிறந்த தேதி : வயது

மருத்துவமனை எண் :

நான் எனக்கு அளிக்கப்பட்ட ஆய்வின் தகவல் படிவத்தை படித்து புரிந்துகொண்டு சந்தேகங்களை கேட்டு அறிந்துக்கொண்டேன் ( )

இந்த ஆய்வில் எனது குழந்தை பங்குபெற என்னுடைய சொந்த விருப்பத்தின் பெயரிலேயே அனுமதிக்கின்றேன். மேலும் இந்த ஆய்விலிருந்து எப்போது வேண்டுமானாலும் விலகிக்கொள்ளலாம். இதனால் எனக்கு வழங்கப்படும் சிகிச்சையில் எவ்வித பாதிப்பும் ஏற்படாது என்றறிவேன் ( )

இந்த ஆய்விற்காக என்னுடைய குழந்தைக்கு உபயோகிக்கப்படும் முறை (அ) அதன் பற்றிய தகவல் எனக்கோ (அ) எனது குழந்தையின் மருத்துவருக்கோ தெரியாது என்பதை அறிவேன். ( )

இந்த ஆராய்ச்சியினால் ஏதேனும் பாதிப்பு உண்டாகுமாயின், அதற்காக இலவசமாக வைத்தியம் அளிக்கப்படும் என்றும், மேலும் இந்த ஆராய்ச்சியில் பங்குபெற எனக்கு பணம் ஏதும் வழங்கப்படாது என்பதையும் அறிவேன். ( )

நான் இந்த ஆய்விலிருந்து விலகினாலும் எனது குழந்தையின் மருத்துவ தகவல்களை மருத்துவர்களுக்கும் நிறுவனத்தின் நெறிமுறைக்குழுவைச் சேர்ந்தவர்களுக்கும், தகவல்கள் அறிய அனுமதி அளிக்கின்றேன். ( )

எனது குழந்தையின் பெயரோ (அ) அடையாளமோ மூன்றாவது நபருக்கு தெரிவிக்கப்படமாட்டாது என்பதை அறிவேன். ( )

எனது குழந்தையை இந்த ஆய்வில் பங்கேற்க அனுமதியளிக்கிறேன்.

பெயர் (கையொப்பம்)

(அ) கட்டைவிரல் ரேகை பதிவு

பங்கு பெறுபவருக்கு இருக்கும் தொடர்பு:

சாட்சியாளரின் கையொப்பம்:

ஒப்புதல் பெறுபவரின் கையொப்பம்:

இந்த இரண்டு முறையும் தற்போது நடைமுறையில் உள்ளது.

1. இந்த ஆய்வின் மூலம் எந்த முறை சிறந்தது என்று ஆராயப்படும். தாங்கள் இந்த ஆய்விற்கு ஒப்புதல் அளித்தால் தங்கள் குழந்தைக்கு மேற்குறிப்பிடப்பட்ட இரண்டு முறைகளில் ஏதேனும் ஒரு முறையின் மூலம் மூச்சுக்குழாயின் அளவு எடுத்து பின் சரியான அளவு கொண்ட மூச்சுக் குழாய் பயன்படுத்தப்படும்.

2. இந்த ஆய்வில் பங்குபெற பணம் செலுத்த வேண்டுமா?

இந்த ஆய்வில் பங்குபெற தாங்கள் எந்த பணமும் செலுத்த தேவையில்லை

3. இந்த ஆய்வில் பங்குபெற ஊதியம் தரப்படுமா?

இந்த ஆய்வில் பங்குபெறுதல் தங்களின் விருப்பமே.

பங்குபெறுவதற்காக ஊதியம் எதுவும் தரப்படாது.

4. இந்த ஆய்வில் நான் பங்கேற்க மறுத்தால் என்ன ஆகும்?

இந்த ஆய்வில் பங்குபெறுதல் தங்களின் சொந்த விருப்பமே, ஆய்வில் பங்குபெறாவிட்டாலும், உங்கள் குழந்தைக்கு சிறந்த சிகிச்சை நிச்சயமாக வழங்கப்படும்.

5. இந்த ஆய்வில் இருந்து விலக முடியுமா?

இடையில் இந்த ஆய்விலிருந்து விலக முடியாது. ஆனால் நீங்கள் இந்த ஆய்வில் பங்குபெற ஒப்புதல் தர மறுக்கலாம்.

6. இந்த ஆய்வில் பங்குபெறுவதால் என்ன பயன்?

இந்த ஆய்வின் முடிவை கையாண்டு வருங்காலங்களில் குழந்தைகளுக்கு சரியான அளவுடைய மூச்சுக்குழாய் பயன்படுத்த உதவியாக இருக்கும்.

7. இந்த ஆய்வில் ஏதேனும் பாதிப்புகள் ஏற்படுமா?

இந்த ஆய்வின் மூலம் தங்கள் குழந்தைக்கு எந்த பாதிப்பும் ஏற்படாது. இந்த இரு முறைகளும் ஏற்கனவே நடைமுறையில் உள்ளது.

8. இந்த ஆய்வில் தங்கள் குழந்தையின் பெயரோ அல்லது மற்ற தகவலோ வெளியிடப்படுமா?

தங்கள் குழந்தையின் வயதை தவிர எந்த ஒரு அடையாளத்தையும் வெளியிடமாட்டோம். இந்த ஆய்வின் முடிவை அறிவியல் பயனுக்கு உபயோகிக்கப்படும்.

9. மேலும் எனக்கு சந்தேகம் ஏதும் இருந்தால் யாரை தொடர்பு கொள்ள வேண்டும்?

உங்களின் சந்தேகங்களுக்கு மருத்துவர் "ரீனா பால்" அவர்களை எந்த நேரத்திலும் தொடர்பு கொள்ளலாம்.

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முகவரி : மயக்க மருந்துத் துறை
கிறுத்துவ மருத்துவ கல்லூரி
வேலூர் 632 004

Master Sheet

PT ID.	AGE (MTHS)	sex M-1 F-2	WEIGHT (KG)	HEIGHT (CM)	ASA GRADE	ETT AGE BASED	SUBGLOTTIC DIAMETER USG	ETT BY USG	ETT USED	OUTER DIAMETER OF ETT	CORRECT METHOD	NO. OF ATTEMPTS	LENGTH OF ET AGE BASED	CORRECT LENGTH TUBE	MATCH
S1	48	2	13.8	99	1	5	6.7	5	5	6.9	BOTH	1	14	14	YES
S2	48	2	15	99	1	5	6.7	5	5.5	7.6	NONE	2	14	13	NO
S3	42	2	14.8	93	2	5	7.4	5.5	5	6.9	AGE	1	13.5	14	NO
S4	19	1	12.7	83	1	4	6.9	5	5	6.9	USG	2	12.5	13	NO
S5	48	1	14.8	98	2	5	7.3	5.5	5.5	7.6	USG	2	14	14	YES
S6	8	1	7.3	66	2	3.5	5.5	4	4	5.5	USG	1	11	10	NO
S7	4	1	6.06	60	1	3.5	5.4	4	4	5.5	USG	1	11	10	NO
S8	33	1	12	93	2	4.5	7.7	5.5	5.5	7.6	USG	2	13	13	YES
S9	5	1	6.38	68	2	3.5	5.2	4	4	5.5	USG	1	11	11	YES
S10	60	1	13.8	100	1	5	7.6	5.5	5.5	7.6	USG	2	14.5	14	NO
S11	36	1	14	110	1	5	8.8	6	5.5	7.6	NONE	2	13.5	13.5	YES
S12	24	1	12	95	1	4.5	7.4	5.5	5.5	7.6	USG	2	13	13	YES
S13	54	1	17	107	1	5	7	5.5	5.5	7.6	USG	2	14	14	YES
S14	0.4	1	4.25	48	1	3	5.1	4	4	5.5	USG	2	9	9	YES
S15	12	2	7.6	75	1	4	5.9	4.5	4.5	6.2	USG	1	12	10	NO
S16	14	1	9.9	71	1	4	5.6	4.5	4.5	6.2	USG	1	12	12	YES
S17	18	2	9.5	78	1	4	5.1	4	5	6.9	NONE	1	12	10	NO
S18	12	2	10.4	74	1	4	5.3	4	4.5	6.2	NONE	1	12	12	YES
S19	18	1	11.4	88	1	4	5.7	4.5	4.5	6.2	USG	1	12	14	NO
S20	60	1	13.8	108	1	5	7.1	5.5	5.5	7.6	USG	2	14.5	14	NO
S21	12	2	9.2	71	1	4	5.3	4	4.5	6.2	NONE	2	12	11	NO
S22	72	2	15.8	112	1	5.5	6.2	4.5	5.5	7.6	AGE	1	15	15	YES
S23	48	2	17.2	110	1	5	6.2	4.5	5.5	7.6	NONE	1	14	14	YES
S24	24	1	12.9	91	1	4.5	5.8	4.5	4.5	6.2	BOTH	1	13	13	YES
S25	24	1	13.2	87	1	4.5	6.6	5	5.5	7.6	NONE	2	13	13	YES
S26	60	1	23.9	119	1	5	7.7	5.5	5.5	7.6	USG	1	14.5	14	NO
S27	12	2	7.9	76	1	4	5.6	4.5	4.5	6.2	USG	1	12	13	NO
S28	24	1	15.6	100	1	4.5	7.7	5.5	5.5	7.6	USG	2	13	14	NO
S29	1	1	3.2	52	2	3	4.5	3.5	3.5	4.8	USG	1	10	9	NO
S30	12	1	11.5	74	1	4	6.7	5	5	6.9	USG	2	12	12	YES
S31	3	1	6.7	62	1	3.5	5.1	4	4	5.5	USG	2	10	10	YES
S32	48	1	13	91	1	5	6.7	5	5.5	7.6	NONE	2	14	13	NO
S33	48	1	19.8	112	1	5	7	5	5.5	7.6	NONE	1	14	15	NO
S34	24	1	11.8	88	1	4.5	6.7	5	5	6.9	USG	1	13	13	YES
S35	48	2	17.3	105	1	5	6.2	4.5	5	6.9	AGE	2	14	13.5	NO
S36	36	2	11.5	91	1	5	6.3	4.5	5.5	7.6	NONE	1	13.5	13.5	YES
S37	14	1	9.1	78	1	4	5.9	4.5	4.5	6.2	USG	1	12	12.5	NO
S38	15	1	11.3	72	2	4	5.2	4	4.5	6.2	NONE	1	12	12.5	YES
S39	60	2	16	107	1	5	6	4.5	5	6.9	AGE	2	14.5	14	NO
S40	60	1	14.7	106	1	5	6.5	5	5.5	7.6	NONE	1	14.5	13.5	NO
S41	24	2	12.2	94	1	4.5	5.7	4.5	4.5	6.2	BOTH	2	13	11	NO
S42	48	1	11.8	95	1	5	6.1	4.5	5	6.9	AGE	1	14	14	YES
S43	2	1	5	57	1	3	4.7	3.5	3.5	4.8	USG	1	10	9	YES
S44	36	2	11.6	92	1	5	5	4	5	6.9	AGE	1	13.5	12	NO
S45	12	1	10.5	71	1	4	5.9	4.5	5	6.9	NONE	2	12	12	YES
S46	24	1	10.2	85	1	4.5	6.4	5	5	6.9	USG	2	13	12	NO
S47	12	1	10	75	1	4	5.8	4.5	4.5	6.2	USG	1	12	12	YES
S48	48	1	12.7	97	1	5	6.9	5	5	6.9	BOTH	1	14	13	NO
S49	36	2	11	98	1	5	6.6	5	5	6.9	BOTH	1	13.5	12	NO
S50	48	1	13.6	88	1	5	6.6	5	5	6.9	BOTH	1	14	13	NO
S51	6	1	5.4	62	2	3.5	4.8	3.5	3.5	4.8	BOTH	1	11	11	YES
S52	24	1	11	82	1	4.5	6.6	5	5	6.9	USG	2	13	12	NO
S53	11	1	8.2	77	1	4	5.1	4	4	5.5	BOTH	2	12	10.5	NO
S54	36	1	14.3	100	1	5	6.4	5	5	6.9	BOTH	1	13.5	14	NO
S55	12	1	9.6	79	1	4	5.2	4	4	5.5	BOTH	2	12	12	YES
S56	6	2	6.4	66	1	3.5	4.8	3.5	4	5.5	NONE	1	11	9.5	NO
S57	24	1	11.9	90	2	4.5	6.5	5	5	6.9	USG	1	13	13	YES
S58	36	1	13	94	2	5	6.2	4.5	5	6.9	AGE	1	13.5	13	NO
S59	60	1	18	110	1	5	6.8	5	5	6.9	BOTH	1	14.5	14	NO
S60	0.5	2	3.08	47	1	3	4.6	3.5	3.5	4.8	USG	1	9	9	YES
S61	60	1	15.3	104	1	5	7.3	5.5	5	6.9	AGE	1	14.5	13	NO
S62	24	2	9.4	82	2	4.5	6.2	4.5	4.5	6.2	BOTH	1	13	12	NO

S63	3	1	6.4	62	2	3.5	4.8	3.5	3.5	4.8	BOTH	2	10	10	YES
S64	17	1	11.5	79	1	4	6.2	4.5	4.5	6.2	USG	1	12	14	NO
S65	6	1	7.4	68	2	3.5	5.3	4	4	5.5	USG	3	11	10	NO
S66	23	1	11.56	80	1	4.5	6.6	5	5	6.9	USG	2	13	12	NO
		1- MALE				4.37121	6.15758	4.62121	4.7803		13 BOTH		12.689394	12.3485	28 yes
		2- FEMALE				0.64635	0.9172	0.62055	0.6147		14 NONE		1.4324942	1.61714	36 NO
						3 to 5.5	4.6 to 8.8	3.5 to 6	3.5 to 5.5		8 AGE		9 to 14. 5	9 to 14	
											31 USG				